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DRUG INDUSTRY ACT OF 1962

WEDNESDAY, AUGUST 22, 1962

HOUSE OF REPRESENTATIVES,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The committee met, pursuant to recess, at 10:15 a.m., in room 1334, New House Office Building, Hon. Oren Harris (chairman of the committee) presiding.

The CHAIRMAN. The committee will come to order.

The first witness this morning, as we resume the hearings on H.R. 11581 to amend the Federal Food, Drug, and Cosmetic Act, will be the Honorable Daniel K. Inouye of Hawaii. We are happy to have you with us, Mr. Inouye.

STATEMENT OF HON. DANIEL K. INOUYE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF HAWAII

Mr. INOUYE. Mr. Chairman and members of the committee, I would like to express my appreciation for this opportunity to be heard on those provisions of title II of H.R. 11581 which would authorize Government inspectors to examine at will the files and records of all food product manufacturers.

As the committee well knows, Hawaii is the leading canned pineapple producer in the world, and is one of the major sugar producing areas. These two products, which are basic to the economy of Hawaii, along with other food products such as coffee, canned fish, and fresh fruits, accounted for an extremely large percentage of our exports in 1961. For the year 1960–61 the last for which complete statistics are available, almost 35 million cases of pineapple and pineapple juice were packed in Hawaii, and the great percentage of this production eventually found its way to the tables of consumers in every town and city in America.

Because of the importance of the pineapple and other food-producing industries to Hawaii, any proposed Government legislation that would seriously affect those industries is of primary concern to every citizen of Hawaii, and to those millions of consumers who rely upon the continuing flow of high-quality food products from the islands to the mainland. For this reason, I have asked to be permitted to testify in opposition to those portions of title II of H.R. 11581 that would amend section 704 of the Federal Food, Drug, and Cosmetic Act to permit FDA employees to enter any food manufacturing establishment and inspect—

all things therein (including records, files, papers, processes, controls, and facilities) bearing on * * * violations or potential violations of this Act.

In my view, this unprecedented grant of authority to a Government agency to pry into the files and records of private commercial enterprises on a regular and recurring basis is not only unwarranted and totally unnecessary, but it would conflict with the basic constitutional prohibition against unreasonable search and seizure, found in the fourth amendment. No evidence has been produced to establish the need for this drastic proposal. On the contrary, there is compelling evidence to establish that this unlimited authority in a Federal agency to enter food manufacturing establishments at will and rifle through their files may well seriously interfere with the efforts of reputable, progressive companies to produce high-quality, wholesome foods on a volume basis at a reasonable price to consumers.

During the course of my years here in Washington, I have come to respect, as has every other Member of Congress, the unceasing efforts of those in the Federal Food and Drug Administration on behalf of American consumers. It is possible that no other Federal agency carries out its assignments with the energy and dedication that are found in the FDA. Because of this well-earned reputation, the FDA has generally received a favorable reception here in Congress when it has requested new authority or amendments to old authority under the Federal Food, Drug and Cosmetic Act.

I sincerely believe, however, that that part of title II of this bill which would throw open the confidential files of all food manufacturers to every FDA inspector would be a grant of Federal power so at variance with fundamental concepts of democratic government and our basic views concerning the constitutional protection against unreasonable search and seizure, that no Congressman can afford in this instance to sit back and accept the proposal on the ground that it appears to be merely another FDA request for authority it claims is necessary to enforce the act.

It is my understanding that this bill is basically a drug proposal that has been broadened to include food manufacturing establishments, apparently on the assumption that what is thought to be necessary for drugs is also necessary for foods. It does not take an expert to realize that foods and drugs are by their nature entirely dissimilar, serving different purposes and subject to entirely different production and distribution techniques. Whether or not this greatly broadened factory inspection authority is necessary for drugs, and there is in my mind a great deal of doubt on that score, it seems clear that there has been no showing that this unprecedented invasion of the confidential and private records of commercial food enterprises is either necessary or desirable.

The record of the American food industry is unquestionable. Anyone who has been through a modern pineapple canning establishment would not question that these packers are taking the greatest conceivable pains to provide consumers with a high-quality, wholesome product that in every degree complies with all requirements of Federal and State laws. Certainly no question has been raised by the proponents of this measure concerning the wholesomeness of the American food supply, for it is recognized on all sides that American consumers enjoy the best food supply in the world.

Perhaps the most that can be said for title II of this bill, at least insofar as it applies to foods, is that it will simplify somewhat FDA's enforcement of the act. But in my mind this is a weak justification for a measure that would seriously threaten important constitutional rights, invade the privacy of every commercial food manufacturer in the country, subject food processors to expensive and delaying harassment, and create unfounded suspicions concerning their operations. I do not feel the time has yet come that administrative convenience or simplified law enforcement can be used to justify this kind of Government authority that runs counter to our basic beliefs concerning the Constitution and the rights of citizens to be free of unnecessary Government interference.

Other witnesses will doubtless cover in greater detail the basic objections to title II of H.R. 11581, at least insofar as it applies to food establishments. It is my understanding that no court has upheld authority such as here requested, and that serious questions under the search and seizure provisions of the fourth amendment would be raised if this part of the bill is enacted into law. As this committee well knows, that question was exhaustively and ably debated in 1953 when section 704 was enacted in its present form. In my mind the decision of this committee and Congress at that time was eminently wise. It was felt then that plant inspection by Federal agents in conjunction with the private efforts of all food manufacturers, would be ample to assure American consumers an unquestionably wholesome food supply. I know of nothing that would justify changing that conclusion.

I sincerely hope every Member of Congress will give his serious and close attention to this proposal. I cannot believe that Congress is yet ready to adopt legislation based on administrative convenience that would throw aside basic constitutional principles that have existed since the founding of this country.

For these reasons I urge upon this committee that they not recommend the adoption of title II of H.R. 11581 as it applies to foods.

The CHAIRMAN. Thank you for your statement, Mr. Inouye.

If there are no questions, we are now honored to have with us our colleague from New York, Seymour Halpern.

STATEMENT OF HON. SEYMOUR HALPERN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. HALPERN. Thank you, Mr. Chairman. I am here today to testify for H.R. 11581 which, in my estimation, is at the very least necessary if the public health of our Nation is to be safeguarded effectively. I have long been concerned with the needs of greater protection for our citizens in this area, and was an original cosponsor of the Kefauver bill.

Therefore, I would like to urge the committee to consider the need for amendments in two areas not embodied in the present bill—licensure and patents. Provisions in these areas were embodied in the bill I introduced several months ago, and while heartily supporting the great strides down the road to greater drug safety and efficacy embodied in H.R. 11581, I am convinced that licensure and patent requirements would push us even further ahead on this road.

Of course, I offer my complete support to the provisions of this bill which should not only provide the public with safer and more efficacious drugs but should also enable our doctors to receive the necessary information for more fully and effectively utilizing the many drugs made available by the progressive efforts of our pharmaceutical firms.

Though the U.S. drug regulations have been praised as the most comprehensive standards of any country in the world, the recent and highly regrettable thalidomide tragedy has left no doubt that the need for extending and revising the existing law is dire. The existing drug regulations, the conscientious efforts of the U.S. pharmaceutical firms, and the strong and knowledgeable stand taken by Dr. Kelsey enabled the United States to escape the magnitude of the thalidomide tragedy suffered in several European countries, but we cannot afford to disregard the warning implicit in the belated discovery of the deforming effects of this drug; we cannot ignore the fact that the drug was received for investigational use by some 1,073 U.S. doctors before the supposedly mild tranquilizer was known to be an abhorrent enemy to the public safety.

We must realistically evaluate existing regulations and, through comprehensive and perceptive legislation, offer greater safeguards to the health of the American people. I am thoroughly convinced that the additional safeguards provided by H.R. 11582 are essential to strengthen the existing legislation.

The bill, as introduced by Mr. Harris in the House of Representatives on May 3, 1962, aims at providing a safer and more effective drug supply for public use, more thorough and comprehensive drug information for the Federal Drug Administration, greater assistance to the drug industry in its efforts to improve the quality and safety of its products, and more honest drug advertisements to enable physicians to better utilize the large and continuously changing drug supply.

In the area of drug safety, section 101 of the bill grants the Secretary of Health, Education, and Welfare the authority to remove a drug from the market immediately if doubts arise as to its effectiveness or safety. The main difference in this provision and the existing one is that at the present the Government bears the burden of proving that a drug is unsafe or ineffective. The amendment places the burden of proof upon the manufacturer, so that drugs will not be marketed unless the sponsor has presented sufficient evidence that they are not only safe, but that they do what is claimed.

The extension of the Federal Drug Administration's approval time from 60 to 90 days or 180 days if an extension is desired, and the requirement of more detailed reports to the Federal Drug Administration on clinical investigations and findings by the manufacturer further augment the plan for more reliable drug approval and offers increased protection to the consumer.

The safety and efficacy of antibiotics will also be enhanced by the regulation requiring batch-by-batch certification of all antibiotics except those exempted by the Secretary. The complexity of the manufacturing process and the seriousness of cases treated with antibiotics make such regulations not only desirable, but necessary.

Section 112 of H.R. 11581, calling for the printing of the generic name in type equivalent to the brand name on drug labels, and a list-

ing of ingredients, promotes the interests of the medical profession and the consumers by simplifying drug terminology and classification.

We do, however, need additional provisions, as I stated at the outset, in the areas of licensure and patents. First, to prevent the use of license agreements as a means of fixing prices, establishing international cartels or otherwise restraining trade, license agreements under patent applications and issued patents should be filed with the Patent Office to be available for inspection and use by the antitrust agencies. Second, to bring about price reductions of those patented drugs whose prices are excessive, patents should be licensed after 3 years to qualified applicants upon a payment of a royalty of up to 8 percent where it is found that the price to druggists is 500 percent or more of the factory cost, including research.

The excessively high prices of drugs as revealed by the Kefauver investigations point out the pressing need of patent laws which do not allow drug production monopolies. Lifegiving drugs should not be prohibitive in price.

Finally, I feel that a program of licensure to insure the continued chemical structure, strength, quality, purity, safety, and efficacy of the products of drug companies and the revoking of licenses of companies not meeting the standards would be a more effective and efficient form of enforcement for maintaining the standards upheld by this bill than the method of seizure proposed in the present form.

I am hopeful that the committee will evaluate and consider the additional proposals I have presented. The above points are representative of the desirable and badly needed drug amendments embodied in H.R. 11581. I wholeheartedly support the passage of this bill created to insure greater protection to the health of America.

The CHAIRMAN. Thank you, Mr. Halpern. If the committee has no questions let us continue to our next witness, Mr. Benjamin G. Habberton, counsel for the Dairy Industry Committee, residing here in Washington.

Mr. Habberton?

STATEMENT OF BENJAMIN G. HABBERTON, ESQ. (FISTERE & HABBERTON, ESQS.), COUNSEL, DAIRY INDUSTRY COMMITTEE

Mr. HABBERTON. Mr. Chairman and members of the committee, my name is Benjamin G. Habberton, and I am a member of the law firm of Fistere & Habberton. I am appearing for the Dairy Industry Committee, for which organization our firm is counsel.

The Dairy Industry Committee is composed of official representatives of a number of national trade associations. These associations are as follows:

American Butter Institute.
American Dry Milk Institute.
Evaporated Milk Association.
International Association of Ice Cream Manufacturers.
National Cheese Institute.
National Creameries Association.
Milk Industry Foundation.

The members of the first six of these organizations are manufacturers of the products which their names suggest. The members of

the last—Milk Industry Foundation—are processors of fluid milk and other fresh fluid products. The members of these associations collectively come from every State in the Union and collectively they account for a majority of all the milk and other dairy products which are processed and delivered in the United States.

At its meeting held in Chicago on June 11, 1962, the Dairy Industry Committee expressed its strong disapproval of H.R. 11581 and authorized this appearance in opposition to the bill.

The opposition of the Dairy Industry Committee is based upon its conviction that title II of the bill, which has to do with factory inspection, is unnecessary and unwise. With title I of the bill, having to do with drugs, the Dairy Industry Committee is not concerned and takes no position.

DAIRY INDUSTRY COMMITTEE FAVORS FACTORY INSPECTION

Before discussing the reasons for its opposition to the factory inspection provisions of H.R. 11581, I wish to make it quite clear that the Dairy Industry Committee is not opposed to factory inspection but on the contrary is in favor of factory inspection and has supported factory inspection legislation.

In 1953 the Committee on Interstate and Foreign Commerce had before it for consideration a bill which proposed amending section 704 of the Federal Food, Drug, and Cosmetic Act. The Supreme Court of the United States, in the now historic *Cardiff* case, had ruled that a Food and Drug Administration inspector might enter a food establishment and make an inspection there only if the owner, operator, or custodian gave his consent. The Food and Drug Administration was thus left without compulsory inspection authority. Believing such authority essential to the discharge of its duties, the Administration caused to be introduced a bill which authorized entry and inspection as of right.

The Dairy Industry Committee agreed that the Food and Drug Administration should have this compulsory authority and my partner, Charles M. Fistere, acting for the committee, appeared before you on May 20, 1953, in support of the bill.

And so, I reiterate, the Dairy Industry Committee favors factory inspection and will continue to support factory inspection legislation.

But the Dairy Industry Committee cannot support the factory inspection amendments contained in H.R. 11581. In fact, it is our view that these amendments do not relate to factory inspection at all but to business records inspection. Under the existing inspection provisions of section 704 of the act, the Government agent is authorized to inspect every—

> factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

This is certainly the language of factory inspection, and we believe that the inspection of these things constitutes factory inspection. But H.R. 11581, while retaining the denomination "Factory Inspection" for section 704, adds to the enumeration of things that may be inspected "records, files, papers, processes, controls, and facilities."

Now, the inspection of records, files, and papers is obviously something quite different from "factory" inspection as that term has here-

tofore been used and understood. It is not just an extension of factory inspection; it is a new kind of inspection. And so, I shall refer to this new inspection as "business records inspection" in order that this important distinction may not be minimized by the use of the original and quite unobjectionable name.

The Dairy Industry Committee is opposed to this new business records inspection which H.R. 11581 would authorize. It is opposed to it, first, because it is unnecessary.

BUSINESS RECORDS INSPECTING IS UNNECESSARY

The Federal Food, Drug, and Cosmetic Act is described as "An Act to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes." It is the responsibility of the Food and Drug Administration to implement and enforce this prohibition, and to do so, it must have the authority to make reasonable inspections to determine whether foods moving in interstate commerce are in fact adulterated or misbranded. There can be no other legitimate purpose for inspection.

Let us consider the situation of a dairy products plant and see whether the inspector does not already have abundant authority.

The plant will be one in which the traditionally highest standards of sanitation are required and observed. The plant will be characterized by its use of equipment which has been designed and manufactured in conformity with Three A standards. These standards have been worked out over a long period of years through the closest possible cooperation of the manufacturers of the equipment, the users of the equipment, and Federal and State regulatory officials. A very high percentage of all of this equipment is fabricated of stainless steel.

The plant may be a milk plant, that is, a plant in which milk and cream are pasteurized, homogenized, and packaged for sale in fluid form. It may be a plant in which butter or ice cream or cheese is made. Or it may be a plant in which one or more of the various forms of dry, condensed, or evaporated milk are made.

The general formulations for all of these dairy products are well known to the Food and Drug Administration. In the case of some of them, standards of identity have been established by regulations promulgated by the Food and Drug Administration. These standards of identity specify the ingredients which the manufactured product must contain and, as well, the optional ingredients which they may contain. In the case of others of these dairy products, standards of identity have been prescribed by act of Congress itself.

Since we have thus far been speaking of only dairy products, it should be pointed out that under section 401 of the act, the Food and Drug Administration is not only authorized but directed to establish such standards of identity for any food whenever it finds it will "promote honesty and fair dealing in the interest of consumers" to do so.

The industries represented on the Dairy Industry Committee have at no time opposed the establishing of these Federal standards of identity, and with reference to certain products, it has been industry which has proposed that they be established.

With this brief recital of the facts concerning the nature of the "factories" to be inspected and the nature of the dairy products manufactured therein, let us now turn to the inspection itself.

Under existing law the inspector is authorized to see and examine the factory structure and all of the machinery and equipment. He will inspect all of these physical facilities in operation. He will examine them from the viewpoint of sanitation and from the viewpoint of effect of design and fabrication upon sanitation. But, as pointed out above, the highest possible standards for these things are traditional in the dairy products industries, and there is apt to be no problem. In any event, he is completely at liberty to see for himself.

And so the inspection proceeds to what section 704 refers to as "finished and unfinished materials," meaning, of course, the finished dairy product being manufactured and the ingredients being used in the product. This is not difficult. As pointed out above, the Food and Drug Administration already knows the permissible formulations for almost all of these dairy products. There is nothing esoteric about them. If the inspector wishes to determine whether the ingredients are for any reason objectionable, he may take samples and have them analyzed by FDA's laboratory scientists. And if he wishes to determine whether the composition of the finished product is within the permissible formulation established by the standard of identity, again he may take samples and have them subjected to laboratory analysis.

Dairy products, like practically all other food products except fresh fruits and vegetables, are packaged, and so the inspector will want to know about the containers. These may be either cartons, cans, drums, or glass bottles. Here again the subjects of the inspection are at hand and available for sampling and analysis. FDA has already made studies of the materials used in cartons and has not, so far as we know and believe, been hampered in any way by lack of inspection authority.

The inspection thus far has had to do with FDA's responsibility to insure that foods shipped in interstate commerce and not adulterated. But it is responsible also for insuring that goods shipped in interstate commerce are not misbranded. And so, the inspector will want to see all of the labeling materials used on these food products, and under the provisions of section 704 he is entitled to.

It may be added that the inspector is assisted in making his inspection of labeling by the fact that section 403 of the present act requires that the labels of foods for which there are Federal standards of identity shall bear the names of all those optional ingredients which FDA shall require in its standards and also requires that the labeling of all fabricated foods for which there are not Federal standards of identity shall bear the names of all ingredients.

Finally, if the inspector should find adulteration or misbranding, and if it becomes necessary for FDA to resort to compulsory action, there is existing authority for obtaining evidence of interstate shipment in order to establish Federal jurisdiction. We have in mind two kinds of authority. The first is the specific authority contained in section 703 of the act whereby FDA may demand shipping records, for use in civil proceedings, not only from carriers but also from persons receiving or holding the products in question. The second is the gen-

eral authority of orderly and time-honored court process whereby FDA may secure shipping records for use in criminal prosecutions.

We believe that a fair-minded assessment of the existing authority for factory inspection would result in the conclusion: The Food and Drug Administration needs and should have the authority it now has, but such authority is adequate for its needs and requires no "strengthening" or extension. We believe that the kind of factory inspection described above is at once reasonable and efficacious.

In expressing these convictions, we remind the chairman and members of the committee that we are speaking only of food establishments and of dairy products plants more particularly. The Dairy Industry Committee takes no position with reference to any alleged need for greater authority to inspect drugmaking establishments but wishes to point out that the two situations may not be identical or even necessarily parallel.

The convictions we have expressed are, we believe, in complete agreement with the conclusions reached by this committee in 1953. This committee was willing to report favorably on the compulsory inspection bill only because it stopped at factory inspection and did not authorize what we have called business records inspection. Yet the Food and Drug Administration now insists that it needs and must have authority to inspect the manufacturers' own files, papers, and records. The only limitation is that these files, papers, and records should be those bearing upon adulteration or misbranding "or otherwise bearing on violations or *potential* violations of this Act." [Emphasis supplied.]

The breathtaking sweep of this unprecedented request for power must assuredly impose a heavy burden of proof upon its proponents. It would be assumed that in order to feel justified in even presenting such a request, its proponents would point out either a shocking deterioration in the safety of our food supplies or else the happening since 1953 of events auguring the same for the future. Yet the proponents of title II have not even attempted to do the former and have not succeeded in doing the latter.

As to the present state of our food supplies, an official of the Food and Drug Administration has only recently reiterated the statement several times before made by others that they are the purest, safest, and most nutritious in the world. The lack of the additional authority which the Food and Drug Administration requests has not thus far caused any deterioration.

And so we look at the record made before this committee bearing upon the possible need for additional authority to prevent such deterioration from this time on.

Secretary Ribicoff stated on June 19:

> All too often inspectors are treated to a guided tour through the establishment. They are denied access to formula files, complaint files, shipping records, and a great deal more information that is absolutely essential for them to see in order to determine whether the products are being produced in compliance with law.

If it is true that as a result of their submitting to "guided tours" inspectors are failing to ascertain the required information concerning possible adulteration or misbranding, it would seem that they are not doing their duty. What is required in this situation is not more authority but more exercise of the authority which already exists.

Frankly we do not believe there are many inspectors who are submitting to "guided tours" as we understand that term to have been used.

As to the Secretary's statement that it is absolutely necessary for inspectors to see the manufacturer's formula files, complaint files, and shipping records in order to determine whether the products are being produced in compliance with law, we can only say that we are in respectful disagreement. We believe that the factory inspection which we have just delineated is quite adequate to make this determination, and there can be no doubt that for such an inspection there is ample existing authority every step of the way. The Food and Drug Administration is doing very well indeed with the inspection authority it already has, and we see not only no absolute necessity but no necessity at all for this requested authority to examine private business records.

But, says the Secretary, the times have changed, and recent enactments of the Congress have made it necessary that FDA have the authority to inspect business records if it is to discharge the responsibilities those enactments have imposed upon it. He says—

> We are required to establish and police safe tolerances for known poisons in our food supply * * *. Yet we are being denied access to the information in the manufacturing establishment to tell us whether our tolerances are being met.

The Secretary is here speaking primarily of the Food Additives Amendment of 1958.

This is indeed an important piece of legislation, though we are not sure that the use of the scare word "poisons" contributes to a dispassionate assessment of its purpose and effect. It is also legislation that adds to FDA's responsibilities, but we are unable to see that these are responsibilities which require that FDA be authorized to inspect private business records. In fact, insofar as any additional means are required to police this legislation, the food additives amendment itself supplies them.

The principal purpose of the food additives amendment, as this committee knows, is to require that these additives, before being used by the food manufacturer, shall be subjected to rigorous testing to ascertain whether there are levels at which they may be safely used and to require FDA to determine such levels. In enacting the amendment, which has now been incorporated into the act as section 409, Congress took precautionary measures.

For example, it prescribed that FDA shall not permit any use of the additive in question unless it finds—

> that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe.

Congress has prescribed also that no tolerance shall be fixed at a level higher than FDA—

> finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended.

Congress has further prescribed that FDA shall not only fix the maximum quantity of the additive that may safely be used or permitted to remain in or on the food, but also may determine the manner in which the additive may be added to or used in or on the food and may prescribe any directions or other labeling or packaging requirements for the additive as it deems necessary to assure safety of use.

Those are all excellent safeguards, but they go only to the fixing of safe tolerances, and Congress was concerned that those tolerances should not be exceeded in actual use. So it provided that every petition filed with FDA proposing the fixing of a tolerance and the issuance of a regulation must contain, in addition to many other kinds of information—

> a description of practical methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use.

Here, then, is the way Congress, and presumably FDA itself in 1958 intended that FDA should ascertain whether tolerances are being observed. It required that practicable methods be supplied by which FDA can make these determinations. We think it is a good way. The FDA inspector can take his samples of the food in which the additive is used, and the FDA laboratory scientists, using these practicable methods or any others they may prefer, can subject them to analysis and easily ascertain the amount of the additive left in or on the food.

FDA itself, in enforcement regulations promulgated under section 409 of the act, has enlarged the statutory requirement that practicable methods be supplied by the petitioner. These regulations require that—

> The test proposed shall be one that can be used for food control purposes and that can be applied with consistent results by any properly equipped and trained laboratory personnel (21 CFR, sec. 121.51(c)).

The statutory requirement is contained, along with other requirements for the petition, in section 409(b) of the act, and in this connection FDA's enforcement regulation states:

> A petition shall be retained but shall not be filed if any of the data prescribed by section 409(b) of the act are lacking or are not set forth so as to be readily understood (21 CFR, sec. 121.51(g)).

FDA has enforced this requirement quite strictly and has in fact refused even to file a petition in which a practicable method of analysis, satisfactory to it, is not set out.

We believe and submit that analysis is the only method by which it can be determined whether tolerances are being complied with. This is true both as a practical matter and as a question of the rules of evidence. Existing law makes ample provision for such analysis, and the requested authority to inspect files and records for this purpose is wholly unnecessary.

It should not be overlooked that additives are components of foods and that the supplies of these substances in the food plant are readily available for inspection as such, as is also the process by which the additives are introduced.

In concluding this portion of our statement, having to do with the adequacy of existing factory inspection authority and the absence of any necessity for authority to inspect the manufacturers' private business papers and records, we should be remiss if we did not remind this committee that insofar as the responsibility for assuring the safety of our country' food supplies is a responsibility of government, it is one which the Federal Government shares with the governments of the several States and with municipal governments.

You may be sure that States and municipalities are not unmindful of their responsibilities in this area of the law. Pure food is the subject of legislation in every State and in hundreds of municipalities, and, as dairy products manufacturers may be more keenly aware than any other category of food manufacturers or processors, it is not only the Federal Government which knows about inspection as a means of enforcement.

PROPOSED BUSINESS RECORDS INSPECTION IS UNWISE

The second reason for the opposition of the Dairy Industry Committee to title II of H.R. 11581 is that the legislation it proposes would be not only unnecessary but also unwise.

This proposed legislation would affect a very large segment of our industrial economy, and your committee always desirous of avoiding unwise measures, would doubtless be especially desirous of avoiding the endorsement of unwise measures when they are of broad application.

We believe title II unwise, first, because we entertain grave doubts as to its constitutionality. Others who have preceded us in presenting their objections to title II have treated ably and elaborately of this most important one, and for this reason it is unnecessary for us to discuss it. We do request, however, that the chairman and members of this committe give their most earnest consideration to the question of how the provisions of title II can be reconciled with the prohibitions of unreasonable searches contained in the fourth amendment. In our view the inspection of the manufacturers' private files and records which title II would authorize is in fact a most thoroughly unreasonable search, and we should anticipate that title II, if enacted, would fall in its first judicial encounter.

But, aside from this hazard, and even if, contrary to our expectations, title II should survive constitutional attacks, it would still be unwise because it sanctions an erosion of rights which have been enjoyed since the founding of our country. Title II says to the thousands of foods establishments throughout our country to which it applies, your books, records, files, and papers are subject to search, without benefit of warrant, by the employees of an administrative agency of the Government, and this search is subject only to the limitation that it shall bear upon possible adulteration or misbranding or that it shall otherwise bear on violations or potential violations of this act. We can only say that constitutional or unconstitutional, this represents a shocking departure from what has heretofore been regarded as the proper function of Government as we know it.

We believe title II to be unwise, in the second place, because it is unworkable and will not accomplish its purpose.

Any realistic appraisal of the value of this proposal to authorize files and records inspection must take into account the fact that there are some dishonest food processors along with the great majority of honest ones. Cognizance must be taken, too, of the fact that, as the Secretary has pointed out, there are a few fly-by-night operators in food industries as well as a great multitude of established and responsible businessmen.

We respectfully submit that there is a relationship between these facts on the one hand and the facts surrounding food processing and recordkeeping on the other hand. We believe it may be asserted that as a general rule it will be only these very small minorities who would intentionally engage in adulteration, either by the use of impure ingredients or by the use of food additives in amounts excessive of established tolerances. We believe, also, that as a general rule those who would engage in intentional adulteration of their products would not hesitate to engage also, so to speak, in adulteration of their files and records. In short, it is almost inconceivable to us that the FDA inspector would ever find the actual facts reflected in the files and records of such manufacturers.

Correlatively, we respectfully submit that the consumer has nothing to fear from the great majority of honest and established manufacturers. We have pointed out above that the responsibility of the Federal Government for safe food supplies is shared with State and municipal governments. It is shared also with the foods manufacturing industry.

The stake of the foods industry in marketing pure and healthful products is a large one. Historically, the record of the foods industry is not only honorable but highly commendable, and pride exists in industry as in other activities of American life. The history of the dairy products industry, especially, has been quite outstanding. It has been a history characterized not only by a significant and long-continued contribution to the national health but also by a quite negligible incidence of illnesses caused by products that were in any way impure or contaminated.

But aside from such considerations as these, there are impelling factors of self-interest involved in the food industry's responsibility for a safe food supply. All food manufacturers know that the consumer is increasingly aware of product liability. And from the long-term viewpoint, no manufacturer can hope to stay in business if he gains a bad reputation. The authority of FDA under section 705 "Publicity" can, of course, have a great deal to do with this.

In summary, we submit that files and records inspection would not produce the kind of information which its endorsers say it would. It would not produce evidence of adulteration, actual or potential. It would not operate against the sharp dealer and the fly-by-night operator. It would not accomplish its purpose. We sincerely believe that better results would be obtained if the time and expense which files and records inspection would entail were applied to the reasonable factory inspection for which existing law provides.

In the third place, title II is unwise because it would increase the already great disparity between the control exercised by the Food and Drug Administration over foods manufactured in the United States and foods manufactured in foreign countries and imported into the United States. One has only to visit the supermarket to see that foods of foreign manufacture are being imported in large and increasing volume.

Section 801 of the act provides that with reference to any such food (or drug or cosmetic), the Secretary of Health, Education, and Welfare may, upon request to the Secretary of the Treasury, secure a sample of the same. If, from "examination" of this sample, it ap-

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pears that the product is adulterated or misbranded, it may be excluded from the United States unless the consignee causes it to be brought into compliance with law.

But this "examination," if it occurs, and however it is performed, is the only means by which the Federal Government may exercise jurisdiction over this product. Obviously the FDA has no authority whatever to inspect the foreign establishment in which this food product was manufactured, and it would appear to be beyond the power of Congress to give it such authority. Accordingly, there is, and can be, no foreign factory inspection by FDA's inspectors.

This is quite different from the authority exercised over the manufacture of food products in the United States, where the FDA inspector is authorized to inspect plant, operations, processing, and ingredients, as well as the finished product. In short, FDA knows the conditions under which food products are manufactured in the United States. It does not know the conditions under which foods imported into the United States are manufactured.

Yet, title II of H.R. 11581 substantially broadens this conspicuous gap. It says that while foreign food products are admitted without even factory inspection, American food products must be subjected not only to factory inspection but also to private records and files inspection.

We reiterate: This is unwise.

We are not arguing against the import of food products into the United States. We know that it is necessary to import in order to export. But we do urge that this inequality of control over American and foreign food products has gone far enough. Let us not increase it by authorizing the inspection of the records and files of American businesses.

The CHAIRMAN. Does that conclude your statement, Mr. Habberton?

Mr. HABBERTON. It does, Mr. Chairman.

The CHAIRMAN. We appreciate having your views on behalf of the dairy industry.

I am also aware of the fact that the canners have expressed a great deal of concern over the extension of the factory inspection provision.

I had not realized that there would be so much concern among the dairy industry, because I did not think it was involved with formulas and things of that kind.

I do know that there are some very stringent local requirements insofar as the dairy industry is concerned. I imagine in certain types of dairy products there could be some great concern, such as butter, probably, but, generally, I cannot see how it would be of great concern, as it would with a lot of other food products.

I know the industry generally, and I can appreciate that it does not want the Government delving around in their records any more than they could help.

Mr. HABBERTON. Yes, sir.

The CHAIRMAN. That is a basic concept in this country, and I am wholeheartedly in favor of it.

But we do recognize that there are, as you said in the statement, certain areas in which it is necessary. Our society has grown to the

extent that when our needs are provided, certain protections must be also provided for.

What serious objection would your industry advance to keep those who are charged with this responsibility from looking at the complaint files?

Mr. HABBERTON. Well, sir, in the first place, let me say that the dairy industry has great confidence in its products. It has no apologies to make for its products. It has had a long and splendid history of producing healthful and pure products.

The CHAIRMAN. Well, we know all of that, and we agree with it.

Mr. HABBERTON. Yes, sir.

The CHAIRMAN. And if it were not for these few you spoke of a while ago, it would not be necessary to have any.

Mr. HABBERTON. Yes.

The CHAIRMAN. So now let us get down to the basic facts of what we are considering.

Why would there be any objection to it?

Mr. HABBERTON. Well, sir, complaint files generally consist of what is sometimes referred to as raw information.

It has to do with complaints which may concern any one of a large number of things. Some of them may have no connection whatever with the purity of the product or the sanitation of the plant or anything else.

Complaints are received many times from people referred to, correctly or incorrectly, as crackpots.

The CHAIRMAN. I am not talking about complaints generally or whether or not Sam Jones might be a good man or he wears one short-leg pants and a long-leg pants.

I am talking about complaints with reference to a dairy product as to whether or not it is adulterated or misbranded or in violation.

Mr. HABBERTON. Well, we think I would be unfair to the dairy industry for the inspectors to have these complaint files because they are not reliable information. It is unsifted information.

The CHAIRMAN. Well, they are the same kind of information that goes into the Food and Drug Administration, generally speaking, or that comes to a congressional office or some other place, is it not?

Mr. HABBERTON. I do not believe it is, sir; and I think, furthermore, that this is information which FDA can get by other means.

If they have reason to think that anything is wrong, there are certainly established means under the existing law by which they can get this information, without going into complaint files which have always been regarded as the private property of the manufacturer.

It would not produce reliable information for them.

The CHAIRMAN. It would seem to me, insofar as the industry is concerned, that you would want those kind of communications to be seen and then be able to show the inspectors where they are wrong, or, if there is any substance to it, where it has been corrected.

There seems to be a practical situation insofar as industry is concerned that must be met, instead of taking an absolutely negative position on everything.

Mr. Younger?

Mr. YOUNGER. If the complaint files are to be made available, then the complimentary files ought to be made available, also, should they not?

Mr. HABBERTON. I believe that is right, sir.

The CHAIRMAN. Will the gentleman yield?

Mr. YOUNGER. Yes, sir.

The CHAIRMAN. You do not hesitate to make those available, though, do you?

Mr. HABBERTON. Right.

Mr. YOUNGER. They are not called for in the bill.

On page 3, where you say "records, files, papers, controls, and facilities," do you interpret that to mean formulas also?

Mr. HABBERTON. Yes, sir, I certainly do. Undoubtedly, it would include formula files.

Mr. YOUNGER. That is all, Mr. Chairman.

Mr. HABBERTON. Formula files that are the principal source of trade secrets.

The CHAIRMAN. Mr. Glenn?

Mr. GLENN. Sir, I take it, then, that your only objection is to the inclusion in the bill on page 31 of the words "including records, files, papers, processes, controls, and facilities"?

Mr. HABBERTON. That is our principal objection, sir.

Mr. GLENN. And if that is deleted, you will be happy?

Mr. HABBERTON. Well, we object also to the extension of this inspection to laboratories which may be employed by food manufacturers to engage in research and experimentation for them.

We think that is a very vicious provision.

Mr. GLENN. Did you cover that in your statement?

Mr. HABBERTON. I had not said anything specifically on the subject, but we believe that there is certainly a highly confidential relationship between the food manufacturer and the scientific laboratory which it employs to engage in scientific research and experimentation for it.

This work has to do with the products which may be in the very beginning, products which are brandnew, products which are only in process and which have never been manufactured or marketed, and which may never actually be commercially marketed.

This is certainly highly confidential information between the food manufacturer and the scientific laboratory, and we think that it would be a great mistake and distinctly harmful to the food industry and to industry in general for this information to be made available to the FDA inspector.

Mr. GLENN. Thank you very much.

That is all, Mr. Chairman.

The CHAIRMAN. Mr. Hemphill?

Mr. HEMPHILL. Thank you.

I have one question here.

On page 4 you make a statement in the last paragraph:

> The general formulations for all of these dairy products are well known to the Food and Drug Administration.

Does that mean that any formula that you have or use in connection with the industry is known now?

Mr. HABBERTON. Mr. Congressman, those are formulations which are provided for in the Federal standards of identity. There are Federal standards of identity for practically all dairy products, and these are standards of identity which have been promulgated by FDA itself and, in the case of two dairy products, butter and nonfat dry

milk, standards of identity have actually been prescribed by the Congress in legislation.

So that for all of these food products, there are standards of identity, and obviously, they are well known to FDA, which has promulgated them.

Mr. HEMPHILL. But not necessarily standards telling the exact proportions?

Mr. HABBERTON. No, sir.

Mr. HEMPHILL. Or the manner in which they are put together?

Mr. HABBERTON. We think that would involve a great many trade secrets.

Mr. HEMPHILL. That is like Coca-Cola or Pepsi-Cola or something like that; you have the same problem?

Mr. HABBERTON. Yes, sir.

Mr. HEMPHILL. I would suspect, because I have such admiration for the dairy industry, that you people would want to make certain that your products continue to have the highest cleanliness and also food value, would you not?

Mr. HABBERTON. Indeed, we would, sir.

Mr. HEMPHILL. But your objection is to giving access to the books and records?

Mr. HABBERTON. Those, we believe, are the private property of the manufacturer, and in the case of the precise formulations, we think that those clearly involve trade secrets. They are valuable to the manufacturer.

It may be a formula which the manufacturer has developed over a long period of years. He probably thinks it is the very best product that can be manufactured, and he does not want other manufacturers, does not want the public, in general, nor does he want FDA, to know what the exact formulation is.

Mr. HEMPHILL. Suppose the language in the legislation were amended to protect the trade secrets except in those instances where there was some proof first that there was some injurious quality, not just a suspicion, but some fact of injury or harm.

You would not have any objection under those circumstances, would you?

Mr. HABBERTON. Well, sir, we think there is still a great deal of danger from inadvertent disclosure of information of this kind.

It seems to be very difficult to confine it to the manufacturer's files, once the files are open to anybody, whether it is a Government inspector or anyone else.

Mr. HEMPHILL. I understand that, but there are some people, of course, who see danger in everything the Government does, and, yet, those people who write us about the Government are willing to ride in the ships across the ocean on high-priced vacations or take advantage of the subsidies to airlines or write us to help out the railroads or anything else.

It sort of depends on whose ox is gored in this business of the Government being dangerous, is that not about the fact of it?

Mr. HABBERTON. Yes, sir.

Mr. HEMPHILL. Thank you so much.

Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Sibal?

Mr. SIBAL. Mr. Chairman.

I would like to get into the purpose of the request for the right to make the inspection of records.

Mr. HABBERTON. Of what, sir?

Mr. SIBAL. The purpose behind this request.

I do not think anybody can seriously argue with you that it is not proper for the Government to get involved in trade secrets and things of that nature, but it does not seem to me that you can use this as an excuse to brush aside some of the pertinent aspects of records.

Is it your position that if, for example, Mr. Habberton, some evidence, not conclusive perhaps, of impropriety in the production of a particular product cannot be developed further by checking a complaint file to see if there has been a history of complaints about this product, which perhaps might form a pattern, is it your position that this is not relevant and should not be made available to an inspector; not trying to intimidate the industry or to in any way impose himself upon your management, but to find out simply if the public needs some additional protection.

Mr. HABBERTON. Well, sir, we think that this is information which FDA can easily get under its present authority; its authority to take samples of all of these food products, to take samples of all of the ingredients, to analyze them at any time, to do so repeatedly, can go into that just as deeply as it wishes to, and, by doing that, it is getting reliable scientific information as to whether there is any basis for the complaint.

We think that since this information can be gotten by FDA under existing authority, that its authority should not be extended into the realm of the private property, the private files of the manufacturer.

Mr. SIBAL. I want to say that I am well aware of the danger of giving additional inspection rights, particularly in the record field.

Mr. HABBERTON. Yes.

Mr. SIBAL. There have been many pieces of legislation, not only before this committee but before the Judiciary Committee of this Congress, where constant request for additional power which go beyond the traditional scope of Government investigating agencies have been requested, and I certainly agree that we have to be careful and have to watch this very carefully in order to protect basic rights.

But where we have public health as our purpose, it is very difficult for me, as the chairman indicated in his question, to understand why, if a particular product is under investigation, the whole area of public expression, including complaints to the manufacturer, should not be made available to the investigating authorities.

Mr. HABBERTON. Oh, sir, if FDA is actually conducting an investigation of a particular product, in the course of that investigation it can get a warrant and get all of this information.

Mr. SIBAL. It has to go to court.

Mr. HABBERTON. It has that authority under existing law.

Mr. SIBAL. It has to get that warrant through a court process.

Mr. HABBERTON. Yes, sir.

Mr. SIBAL. Do you think it should be required to go to court for that?

Mr. HABBERTON. I think that it should when it is going into private files.

I may add to that that complaints, if they are a matter of interest to FDA, are certainly no less a matter of interest to industry itself.

Certainly the food industry does not want to have dissatisfied customers, whether there is some basis for their complaint or not.

Every complaint which is received, I am sure, by a dairy products manufacturer is considered.

An effort is made to try to determine whether there is some basis for it, and if it should develop that there were some basis for the complaint, naturally, the food industry itself would be the first to want to take any remedial action that might be necessary, because its own self-interest is so closely tied up with matters of that kind.

Mr. SIBAL. Are you not really saying that if you follow your statement through to its logical conclusion, you come to the conclusion there should be no Government inspection; that the food industry would take care of itself?

Mr. HABBERTON. Oh, no, sir, I do not take that position at all.

We think that FDA should have this broad authority which it has to inspect right now, this authority to come into the factory, to look at everything in the factory, to see the entire manufacturing process, to take samples of the food and all the ingredients, to make analyses.

That is a very broad inspection authority, we think, and we think FDA should have it.

We think it should have it by all means, because in the case of these people whom the Secretary referred to as fly-by-night operators, if they are using improper ingredients, certainly FDA ought to know it, and the way for them to learn it is by coming in and taking samples of the ingredients in the foods and conducting their own analyses.

That is the very kind of authority, it seems to us, which will result in FDA's getting the information that it needs and which it must have as a basis for prosecutions.

Mr. SIBAL. So it boils down to the fact, does it not, that if a given person makes a complaint to the FDA, then this complaint is a proper part of the investigation?

Mr. HABBERTON. I think it would be.

Mr. SIBAL. But if the complaint is made to the company, it is not?

Mr. HABBERTON. Well, I think that in either event it is a matter which ought to be pursued by court process rather than by broad, sweeping authority to a Federal inspector to come in and look at all of the plant's files and records.

Mr. SIBAL. Do you think it is possible perhaps to limit this right in some way to strengthen the requested authority of the FDA without opening this door, which I want to make clear I fully understand and am in sympathy with?

Mr. HABBERTON. Yes, I appreciate your position, but I frankly do not believe that it would. I do not believe that it would be possible to limit this additional authority in such a way that it would be satisfactory to FDA and still, in our opinion, still have a constitutional inspection statute.

Mr. SIBAL. Has any discussion been held between the industry and the Food and Drug Administration in this area?

Mr. HABBERTON. There has been discussion, yes, sir; there has.

It has not assumed any definite planning or anything of that kind. There has been incidental discussion. But we believe that if this in-

spection provision were to go beyond its present scope and purpose, that it would infringe upon constitutional guarantees.

Mr. SIBAL. Just one additional question.

Has Secretary Celebrezze expressed himself in this area since he has assumed office?

Mr. HABBERTON. I do not believe that he has made any public expression of his own views, on this. If so, it has not come to my attention.

Mr. SIBAL. So when you refer to the Secretary, you refer to his predecessor?

Mr. HABBERTON. Right, sir.

Mr. SIBAL. Thank you.

The CHAIRMAN. Mr. Dingell?

Mr. DINGELL. Yes, Mr. Chairman. I had a number of questions I wanted to ask the witness, if I might.

You referred to specific power in the Food and Drug Administration to secure information, books, records, and so forth.

You referred to section 703 whereby the FDA may demand shipping records for use in civil proceedings.

Now, does this section deal only with shipping records or is it more broad?

Mr. HABBERTON. It has to do primarily with shipping records.

Mr. DINGELL. I see, with shipping records.

Does it have to do with anything besides shipping records?

Mr. HABBERTON. Not so far as a specific grant of authority is concerned.

Mr. DINGELL. So it has authority to get shipping records only through civil proceedings.

Now, what kind of civil proceedings may it secure these shipping records it, in cases involving seizures, in cases involving misbranding, or in cases involving what?

Mr. HABBERTON. It can get this shipping information without there being any proceeding pending at all.

Mr. DINGELL. Just on shipping?

Mr. HABBERTON. That is right; yes, sir.

Mr. DINGELL. Shipping information as to what, volumes and quantities shipped?

Mr. HABBERTON. And who is the shipper.

Mr. DINGELL. And who is the recipient?

Mr. HABBERTON. Who is the recipient or consignee, and then FDA can take that information and institute a proceeding based upon the information gotten under 703.

Mr. DINGELL. These shipping records to which you refer are solely records of quantities shipped, persons doing the actual shipping and receiving, is that correct?

Mr. HABBERTON. Yes, sir; that is correct.

Mr. DINGELL. And they are no more broad, the shipping records provision is no more broad than that, am I correct?

Mr. HABBERTON. I think that is correct, sir.

Mr. DINGELL. So that, in a sense, then, is a very limited power that the Food and Drug Administration has, is that correct?

Mr. HABBERTON. We think it is a very broad power.

Mr. DINGELL. As a matter of fact, section 703 here says:

> For purposes of enforcing provisions of this act carriers engaged in interstate commerce and persons receiving food and drugs—

and so forth—

> food, drugs, devices or cosmetics in interstate commerce or holding such articles so received shall, upon the request of an officer or employee, duly designated by the Secretary, permit such officer or employee at reasonable times to have access to and to copy all records showing movement in interstate commerce of any food, drug, device or the holding thereof during shipment and the quantity, shipper, consignee thereof.

So this is the only power Food and Drug has to actually look at the bills of lading, is that not correct?

Mr. HABBERTON. That would be the thing they would look at first, I would think.

Mr. DINGELL. But that is actually all they really have the right to do, look at bills of lading, shipping documents and so forth?

Mr. HABBERTON. It enables FDA to make out a case in interstate commerce, and it has complete jurisdiction over the matter, so it is a broad power.

Mr. DINGELL. This only establishes jurisdiction. This section does not in any way apply to the contents of the goods, the food additives used, pesticide chemicals used, the manner of treatment of the commodity in transit, rather the amount of treatment of the commodity as it is manufactured; am I correct; or the way in which it is treated?

Mr. HABBERTON. After it gets this information under 703, it may then seize the food product, if it wishes to do so.

Mr. DINGELL. Now, on what basis can FDA seize, then, this particular commodity?

Mr. HABBERTON. Because it has a right to inspect all food products.

Mr. DINGELL. It has a right to inspect food products. This is exactly it.

Then on the basis of this the Food and Drug Administration has got to go in and has got to take samples; am I correct?

Mr. HABBERTON. Yes, sir.

Mr. DINGELL. This is the limit of their actual power to reach and to investigate the kinds of additives, whether the food or drug is contaminated, dangerous, or unsafe, whether it has claims made for it which are in excess of fact.

This is the limit of the powers of the Food and Drug to actually determine these things, is to go in and take samples and make laboratory analyses; am I correct?

This is the only power Food and Drug actually has concerning what goes into that food, the nature of the food, whether it is clean, wholesome, contaminated, whether it happens to have an excessive amount of chemical additives, whether it happens to have disallowed chemical additives, whether it happens to be unsafe or contaminated, dirty, filthy, or adulterated; is this not correct?

Mr. HABBERTON. You mean it is the authority that they have after it leaves the factory.

Of course, it can do all of these things while the process is going on.

Mr. DINGELL. While it is in the factory by going in and taking samples and then taking them off to have them analyzed; is that not correct?

All right; now, they have general authority to secure shipping records for use in criminal prosecutions; is that not correct?

Mr. HABBERTON. Yes, sir.

Mr. DINGELL. This authority in criminal prosecutions is limited solely to securing shipping records?

Mr. HABBERTON. Yes, sir.

Mr. DINGELL. Am I correct?

So, in effect, the only real authority they have to determine what goes into the food, the nature of the food or the nature of the chemical or medicine is the power that they have to make a chemical analysis of the food; is that not correct?

Mr. HABBERTON. Well, sir, let me go back to——

Mr. DINGELL. The only authority they have, according to your testimony, is to make a chemical analysis of the food.

This is the only statutory authority the Food and Drug has is to actually make a chemical analysis of the food; is this not right?

Mr. HABBERTON. No, sir; it is not because many times no analysis at all is necessary.

It may be quite evident merely by visual inspection of the product that it is contaminated or deteriorated and analysis would not even be necessary.

Mr. DINGELL. Let us concede that this is true. But there are large numbers of additives present in minute amounts in food today which are very difficult to determine by other than very complicated chemical analysis?

Mr. HABBERTON. Yes, sir.

Mr. DINGELL. Involving a great deal of time?

Mr. HABBERTON. Yes, sir.

Mr. DINGELL. Involving a great deal of skill.

In some instances on the order of a few parts per billion; is this not correct.

Mr. HABBERTON. I believe there are no tolerances expressed in terms of parts per billion. There are, of course, many expressed in terms of parts per million. And as pointed out in our prepared statement, FDA can enforce each of these tolerances by use of the practicable method of analysis approved by it at the time it established the tolerance.

Mr. DINGELL. So you propose to continue limiting the Food and Drug Administration to the power to analyze on the basis of a batch-by-batch and a sample-by-sample basis through very complicated, analytical, chemical procedures, and based on an investigation-by-investigation basis.

As a matter of fact, your objection lies to the fact that Food and Drug could, if this bill is passed, go in, look at laboratory records to determine what the company's own records say with regard to manufacturing practices, with regard to quantity and types of additives; is this not correct?

This is your objection to permitting the Food and Drug to go in and to do these?

Mr. HABBERTON. It is one of our objections.

Mr. DINGELL. This is your principal objection, as I read your statement.

Mr. HABBERTON. We object to it on many grounds, as pointed out in our prepared statement.

Mr. DINGELL. I see.

Well, what are your other grounds? What are your other grounds of objection?

Mr. HABBERTON. Well, sir, we object to the extension of this authority to all kinds of books and records, not just merely to formulations.

Mr. DINGELL. Supposing we were to limit it to books and records dealing with manufacturing. Would this eliminate your objection?

Mr. HABBERTON. Dealing with manufacturing?

Mr. DINGELL. Yes.

Manufacturing, the quantity, quality, and types of additives and dealing with the nature and the character of the foods. Am I correct? Would you object to this?

Mr. HABBERTON. I do not know just what would be included within the term "manufacturing."

Mr. DINGELL. I yield to my colleague from California.

Mr. MOSS. It just would seem to me at that point that formulas, controls, ingredients actually received and used certainly would be records bearing directly upon manufacture.

Mr. DINGELL. If we limit it to records bearing on manufacture, do you have any objection, then?

Mr. HABBERTON. We still think that it is an unwarranted and unnecessary extension.

Mr. DINGELL. Very well.

Let us take a look at this, then.

You tell us that this is an unwarranted extension. The present power of the Food and Drug entitles them to station an inspector upon the premises; is that not right?

Mr. HABBERTON. Yes, sir.

Mr. DINGELL. To conduct a continuing chemical analysis; is this not correct?

Mr. HABBERTON. He can stay here as long as he wishes to.

Mr. DINGELL. And to scrutinize the exact processes?

Mr. HABBERTON. Yes, sir.

Mr. DINGELL. But he has no power to determine what has taken place previous to the time he enters the scene or what is needed to protect the American people from contaminated and adulterated lots that may have proceeded through; is this not correct?

Mr. HABBERTON. No, sir, I do not think it is.

Mr. DINGELL. The only power he has is with reference to lots that have already gone through—interstate seizure—is that not correct?

Mr. HABBERTON. He is charged with the protection——

Mr. DINGELL. I know he is charged, but he does not have any power to do more than this.

Mr. HABBERTON. No, sir; that is not correct.

Mr. DINGELL. I recognize he is charged, but he does not have any more power than this.

Mr. HABBERTON. I think he does have the power: I think he has the authority.

Mr. DINGELL. You told me his power is limited to seizing of records to show that the shipments are in interstate commerce.

Mr. HABBERTON. That is what he has as a result of section 703.

Mr. DINGELL. Then he has the power of taking a batch-by-batch basis to make chemical analysis to determine residues that are present, chemical additives, amount of them, and so forth.

This may take a substantial period of time, may it not?

Mr. HABBERTON. Yes.

Mr. DINGELL. So, in effect, what you object to really is to workable factory inspection.

Mr. HABBERTON. Oh, well, we think they have workable factory inspection right now. We think that is exactly what FDA has under the present law.

Mr. DINGELL. As to the factory but not as to the records which would show what exactly goes into the food?

Mr. HABBERTON. Well, it can do better than that under the present law.

It can do better than have the records.

It can follow the food itself. The record would not, as one lawyer to another, sir—the record would not be the best evidence as to a violation. It would be the food product itself which would show the actual contamination or adulteration.

Mr. DINGELL. I recognize this, but the records would make it a great deal easier to prove contamination or to prove unsafe additives, would they not?

Mr. HABBERTON. I do not believe they would, sir.

Mr. DINGELL. It would make it a great deal easier for the Food and Drug Administration to determine whether or not there is an improper additive or contaminant present in the food, would it not?

Mr. HABBERTON. Mr. Dingell, I do not believe for a minute, I just do not believe for a minute that if a sharp operator, a fly-by-night operator, is going to exceed these tolerances, if he is going to adulterate, I do not believe he would ever in the world put those things in his records and files.

Mr. DINGELL. You do not think so?

Mr. HABBERTON. I do not think they would ever appear in his formula files.

Mr. DINGELL. But your opposition to factory inspection would make it a great deal easier for him to do so if he were inclined to, would it not?

Mr. HABBERTON. I think——

Mr. DINGELL. Your opposition to really worthwhile factory inspection would make it a great deal easier for him to have records involving contamination and unsafe manufacturing practices if he were of a mind to keep that kind of records, would it not?

Mr. HABBERTON. If he wanted to keep adulterated records?

Mr. DINGELL. I am not talking about adulterated records. I am talking about factual records of adulterated, unsafe foods, drugs, or cosmetics.

Mr. Moss. Would you yield?

Mr. DINGELL. Let me finish this one question, and I would be happy to yield.

Is this not a fact?

Mr. HABBERTON. No, I do not think it is.

Mr. DINGELL. You do not think it is easier for him to do this?

The CHAIRMAN. I think you ought to let the witness answer, Mr. Dingell. And, furthermore, you have got 17 or 18 pages of his opposition.

Mr. DINGELL. I recognize this, Mr. Chairman.

The CHAIRMAN. If you want to set aside some half day to sit down and argue this, I will be glad to do that.

Mr. DINGELL. I do not want to do that, Mr. Chairman. I just want to scrutinize very carefully his position.

The CHAIRMAN. If you read the 17 pages, I think you will scrutinize his position.

Mr. DINGELL. I have done so, Mr. Chairman.

Mr. MOSS. In the press during this past week I have been interested in noting a case where it would appear that not fly-by-night operators, but an entire segment of the food industry is at least alleged to have, within the meaning of law, adulterated or misbranded its product, and I am referring to the macaroni or pastry.

Mr. FRIEDEL. A little louder, please.

Mr. MOSS. I am referring to the stories now currently being printed about the macaroni or pastry industry where, because of the price of certain ingredients normally used, there has been a substitution.

Now, that is alleged to have occurred.

I have no knowledge other than what I have read in the papers.

But on this product under these conditions I believe that the records of purchase would be the most reliable records on which to form a judgment as to whether or not the misbranding or adulteration has occurred. This is, as I point out, not alleged to have been the action of fly-by-night operators, but, rather, of a very large and responsible segment of the food industry.

So we cannot always, in looking at these provisions, say that they would only be used or it would only be necessary to use them in connection with the fly-by-night, the unstable in-and-outer of the industry.

It could occur. I recall reading in Washington a few years ago of a major processor being charged with certain somewhat similar practices in the manufacture of certain meat products.

It is not too many years ago that I have a recollection, and, again, I am not going to cite names, of a processor in your industry, in the manufacture of certain types of cheese spreads, being charged with the same sort of misconduct, and much of this would be readily ascertainable from pertinent records on manufacture or on acquisition of ingredients.

Mr. DINGELL. Which are not available under present practices.

Mr. MOSS. That is correct.

The only way they get it now is, as you say, by having the inspector there sampling the batches, and through analysis determining this, so that it is a discovery on the spot, but difficult to check on any prior action before the arrival of the inspector.

I would point out that you, as an attorney here, representing your clients, have your responsibility to them. I think we, as representatives of a broader based clientele, have a responsibility to be concerned with the safety, the cleanliness, and the efficacy of the things that they buy, and that we cannot just erect barriers and say we go not beyond this.

We have to carefully evaluate the public interest and the public concern.

But there is a real need in some instances for the access to more records than the shipping records, which really disclose nothing but the consignee and the shipper and the route they travel, minimal records at best, to help you track down something which has been regarded as sufficiently adulterated to cause it to be confiscated.

Mr. DINGELL. I have one more question I would like to ask.

Mr. HABBERTON. I—may I just say a word about this, sir?

Mr. MOSS. Certainly.

Mr. HABBERTON. I think the very kind of information which you say would be gotten from the sales records can also be gotten under section 703 from the records in the hands of the carrier or in the hands of the consignee or holder of the food.

Mr. DINGELL. All that shows is the designation of the commodity——

Mr. MOSS. Let me ask you how that is achieved.

Mr. HABBERTON. After it is found who the shipper is and it is found who the consignee is or the holder is, it can then take the product and do whatever it wants to with it.

If it thinks it is contaminated, it can seize it right there and subject it to analysis.

Mr. MOSS. It might sometimes be a good idea to audit the records of such a manufacturer to determine what his practices have been, whether when he has had a questionable batch, he has shipped it out and gambled with the public health or whether he has pulled it back responsibly and destroyed it or cleaned it up.

Mr. DINGELL. Over and above this, you say that section 703 gives power.

Now, listen to the language of this section:

> For the purpose of enforcing provisions of this Act, carriers engaged in interstate commerce and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such article so received shall, upon request of an officer or an employee.

This is the people to whom this act applies. It does not say anything about processors or manufacturers. It says "carriers and persons receiving."

Mr. HABBERTON. Certainly.

Mr. DINGELL. Now, if the Food and Drug does not have the authority to find out who at the factory site, at the manufacturing point, does not have authority to look at books and records and this section does not give them any authority to look at books and records, the only way they get authority to look at books and records of a person who is operating under their inspection is by initiating a criminal prosecution against the individual, according to the other section that you have cited to us this morning.

So, for all intents and purposes, what you are telling us this morning is that there is no effective inspection of books and records by the Food and Drug on the site.

The section you cite is limited to "carriers and persons receiving." It does not have a word to say about the sender, the manufacturer.

Mr. HABBERTON. Oh, well, certainly——

Mr. DINGELL. I challenge you to tell me where in the section that is.

Mr. HABBERTON. Well, sir, it isn't necessary to challenge me. The purpose of my entire appearance here today is to object to this very thing that you are talking about.

Of course they do not have the authority to inspect files and records.

These suggested amendments would give them that authority, and we are very much opposed to it, and that is why I am here.

Of course, they do not have the authority.

Mr. DINGELL. What you are here, then, to tell this committee is that you, on behalf of your industry, oppose any effective inspection of books and records of manufacturers under the Food, Drug, and Cosmetic Act?

Mr. HABBERTON. We certainly do.

We certainly do oppose the extension of this authority to inspect private files and records. We are very much opposed to that.

Mr. DINGELL. Obviously you must have some reason for this. Have you had a bad experience with the Food and Drug Administration?

Mr. HABBERTON. No.

We have had a very satisfactory experience.

Mr. DINGELL. You have had a very satisfactory experience.

Have you found that in any way they abused the due process clause in their inspections or in their conduct of their relations with your industry?

Mr. HABBERTON. We think that, in general, they have been very circumspect.

Mr. DINGELL. I see.

And there is no reason to think if they get this legislation, they will be other than circumspect, or to continue precisely the same pattern of conduct, am I correct?

Mr. HABBERTON. I think they can act entirely within the letter of the law if these amendments are enacted and still be going far beyond what there is any need for doing, and I think also that if we go beyond the [illegible] of inspection in our inspection provisions, we are getting into fields of unconstitutional enactments.

Mr. DINGELL. I see.

In effect, you are a little bit like the old maid who looked under the bed and sort of hoped she would find somebody was there, am I correct?

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much.

Mr. HABBERTON. Mr. Chairman, may I just say one further sentence on the matter of complaints.

I want to make it clear that manufacturers are interested in complaints. Every complaint that is received by food manufacturers is considered.

If it should happen, as has been suggested by one of the members, that there might be a series of complaints coming from one person, a series of complaints concerning a particular aspect of a product, a particular product, the manufacturer would be the most interested person of all in trying to see that every step was taken that could possibly be taken in order to correct anything that needed correction.

So we think that that is largely a self-policing matter.

The CHAIRMAN. Thank you very much.

Mr. HABBERTON. Thank you very much, sir.

(The following letter was subsequently received for inclusion at this point in the record:)

WASHINGTON, D.C., *August 23, 1962.*

In re H.R. 11581.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce, House Office Building, Washington, D.C.

DEAR CONGRESSMAN: On behalf of the Dairy Industry Committee, I had the privilege of appearing before the House Committee on Interstate and Foreign Commerce on August 22 in opposition to title II—the factory inspection provisions—of H.R. 11581.

As chairman of the committee, you expressed some surprise that the dairy products industries would be opposed to these provisions. I did not at the time fully understand the significance of your comment, and I fear that the explanation which I gave was accordingly not responsive.

I have since that time realized that you were probably thinking more of milk than of other dairy products and felt that such an unsophisticated food could not involve any file or record information which industry would not be glad for FDA inspectors to have access to at all times. It is of course a fact that in addition to milk itself, there are the basic derivatives, namely cream and skim milk in fluid, dried, frozen, or concentrated form, to which no ingredient is added. With respect to such products there obviously would be no formula files.

On the other hand, there are a very large number of dairy products which are fabricated from two or more ingredients and there are Federal standards of identity for practically all of them. Ice cream, for example, does contain numerous ingredients including stabilizers to inhibit the formation of ice crystals, and other components in addition to the dairy ingredients, flavoring, sweetening, and possibly coloring. While conforming with the standard of identity, the individual ice cream manufacturer may very properly feel that his own precise formula makes a better and more popular ice cream than the products made under the slightly different formulas of his competitors.

What I have said about ice cream also applies in large measure to other manufactured dairy products. There are, for example, no less than 65 Federal standards of identity for cheeses, processed cheeses, cheese foods, and cheese spreads, and the manufacture of these foods may, and generally does, involve the use of numerous ingredients other than dairy ingredients.

Accordingly, the records and files of the dairy products manufacturer are as important to him and as much his own valuable property as are the records and files of the manufacturers of any other category of food products.

I shall appreciate your causing this letter to be added to my testimony as part of the record.

Sincerely yours,

BENJAMIN G. HABBERTON.

The CHAIRMAN. Mr. Andrew J. Biemillller.

STATEMENT OF ANDREW J. BIEMILLER, DIRECTOR, DEPARTMENT OF LEGISLATION, AFL–CIO; ACCOMPANIED BY ANNE DRAPER, RESEARCH ASSOCIATE, DEPARTMENT OF RESEARCH, AFL–CIO; AND KENNETH A. MEIKLEJOHN, LEGISLATION REPRESENTATIVE, AFL–CIO

Mr. BIEMILLER. Mr. Chairman, my name is Andrew J. Biemiller. I am director of the Department of Legislation of the American Federation of Labor and Congress of Industrial Organizations.

I am accompanied by Miss Anne Draper, an economist from the Research Department of the AFL–CIO, and Mr. Kenneth A. Meiklejohn, one of our legislative representatives.

I am happy to be here today to testify on H.R. 11581, the Drug and Factory Inspection Amendments of 1962.

The present hearings take on a special urgency because of the recent exposures concerning the drug industry. I refer to America's incredibly narrow escape from general distributions of the dangerous "tranquilizing" drug thalidomide, which had such tragic results in Europe and which, I am sure, is a matter of intense concern to the members of this committee. And I refer also the evidence of unconscionable profiteering in this industry.

Let me dwell for a moment on the recent narrow escape to which I referred. All of us who give drugs to our children or loved ones do so with faith in the doctor who prescribed them, the druggist who compounded the prescription and the industry that manufactured the basic ingredients.

We have to have this confidence. If we don't, then recovery from illness or retention of health are impossible. But how can we have this confidence without basic protective legislation?

Here we have an industry that tried its utmost to bulldoze a dedicated Government into giving a clearance on a drug that the employee suspected was dangerous. Here we have an industry proven to have inflated its prices beyond all bounds of comprehension.

All of us can imagine, I am sure, the uncertainty in the mind of a mother with a sick child. She wants her child to recover; she wants to be sure of the drug she is administering. She needs, and I submit she should have, that confidence and it is within the power of this Congress to give her that peace of mind.

I know that this committee does not have before it the price problem, but I would be derelict if I did not point out that we are urgently concerned over the high prices of many vitally important drugs, and that we consider H.R. 11581 seriously defective in failing to deal with this problem.

We have indicated in testimony before the House Judiciary Committee our strong support for H.R. 6245, the "Drug Industry Antitrust Act," presently pending before that committee, which would effectively deal with it. Here, I must reiterate our view that there is urgent need for legislation to bring down the high price of drugs, as well as to assure their safety and efficacy. Let me add this word about thalidomide. While we are very thankful that the drug was kept off the market, we are also concerned that the drug provisions of the Food, Drug and Cosmetic Act be substantially strengthened all along the line. We can't ever again run the risk of dangerous medicines getting to our population, and I say that on behalf of the 14 million wage-earning families who are members of AFL–CIO unions. The Dr. Kelseys deserve the backing of sound legislation.

We in the AFL–CIO have concerned ourselves with the Food and Drug Act for many years, supporting amendments to strengthen it and seeking adequate appropriations for the Food and Drug Administration to carry out its vital functions.

Our concern about these dual problems is not new, it was set forth in the most recent consumer protection resolution, passed by the

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Fourth Constitutional Convention of the AFL–CIO on December 12, 1961. The pertinent portions read as follows:

The most glaring of the consumer interest issues arising over the past 2 years is that of the high price of prescription drugs, based on monopoly patent rights, restrictive licensing agreements, brand-name promotion and vast outlays for advertising. Drug industry profits, running at 18 percent on stockholders' investment, outstrip those of all other manufacturing industries in the country. Further, the drive for profits has led to irresponsible advertising claims, concealment of dangerous side effects of powerful drug agents, and the subordination of research on useful drug products to the development of inconsequential sales gimmicks of little value to the art of medicine or the ultimate welfare of sick patients. Reforms are clearly called for in behalf of the consuming public.

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Now, therefore, be it resolved:

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We call upon the National Congress to enact legislation that will bring down the high price of prescription drugs, combat misleading advertising by drug companies, and improve the safety and usefulness of drug products generally. To this end we endorse the provisions of S. 1552, and H.R. 6245, pending in the current Congress.

• • • • • • •

We urge new amendments to the Food, Drug and Cosmetic Act to strengthen the powers of the Food and Drug Administration in behalf of the consuming public, including these provided by S. 1552. In addition, power is needed to require manufacturers to pretest therapeutic devices and cosmetic products for safety before putting them on the market.

May I read also the text of a statement issued by the AFL–CIO executive council during its Chicago meeting August 13–16:

We join with the President of the United States and the entire American public in expressing our profoundest congratulations and gratitude to Dr. Frances O. Kelsey, of the U.S. Food and Drug Administration, for her courageous persistence in withholding approval of the dangerous drug thalidomide from the general prescription market. Her action, in the face of strong pressure for its release, is in the finest traditions of public service.

It is a sad commentary, nonetheless, that our present food and drug laws are so inadequate that it takes heroism to administer them properly in behalf of the consuming public. Hopefully the story of the thalidomide tragedies will spur the Congress to enact much needed drug reform legislation in full and undiluted form, such as the AFL–CIO has supported ever since the facts about drug industry practices became apparent from the exhaustive investigations undertaken by the Senate Antitrust and Monopoly Subcommittee, under the chairmanship of Senator Estes Kefauver.

The thalidomide episode has served to highlight one of the very important series of complex and vital issues involved in the legislative proposals growing out of the Kefauver investigations. The safety of drugs is paramount and every effort should be made to see that unsafe and new drugs do not reach the public. Fully adequate animal tests should be required, as a matter of course, before drugs are used even in limited experimental amounts on human beings, and the Food and Drug Administration should be safeguarded from undue industry pressures for hasty approval of inadequately tested drugs.

Additional safety measures needed include more adequate factory inspection powers, for the Food and Drug Administration, the enforcement of manufacturing standards, licensing of drug manufacturers, the addition of tests for efficacy of new drugs as well as for safety, provisions for prompt reporting of adverse side effects of drugs to the Food and Drug Administration, stronger authority to remove hazardous drugs from the market and provisions for seeing that prescribing doctors are fully and truthfully informed as to the efficacy and side effects of drugs.

Further, the general concern for drug efficacy and safety should not be allowed to sidetrack the issue of the high price of drugs. The prescription drug industry is still reaping enormous profits from its patent and brand name monopolies, and charging excessive prices to the public for drug preparations. S. 1552, as

reported out by the Senate Judiciary Committee has been completely stripped of its original patent amendment provisions, which are the key to price reform in this industry. The bill offered by the administration in the House of Representatives, H.R. 11581, is silent on this issue. We strongly urge the prompt adoption of adequate measures not only to insure the safety and efficacy of drugs, but also to bring down the high price of drugs.

The only provisions in H.R. 11581 touching on the price problem are sections 111 and 112 providing for the standardization of drug names and setting out specifications for the printing of the "established name" on drug labels. We fully support the intent of these provisions. Standardization of drug names and the specific requirements for their conspicuous placement on drug labels will aid both the physician and the consumer.

Hopefully, more general usage of the generic name by prescribing physicians will be encouraged so that the consumer will not always have to pay the exorbitant prices commanded by the heavily advertised brand names. We believe, however, that the bill's provisions on labeling should be further strengthened by extending them to advertisements as well, as is now being proposed in the Senate, rather than confining them to drug labels alone.

Very little really can be done, however, to bring down drug prices unless action is taken to deal with the patent monopolies which have been estimated to encompass about two-thirds of all prescription drugs on the market.

Most of the amendments to the Food, Drugs, and Cosmetics Act made by H.R. 11581 relate to health and safety issues. We are naturally in accord with measures which will increase the effectiveness of the protection afforded to the public by the act.

Certain of the proposed provisions have been highlighted by the current thalidomide episode and also recent particular instances where new prescription drugs were actually released to the public without any real knowledge of their dangerous side effects and later recalled from the market only after considerable delay. MER 29 is a clear example. We are aware of the steps taken by the Food and Drug Administration to install more adequate controls over the testing and distribution of such drugs, but we strongly support legislative measures to buttress these regulations and to supply added authority where needed.

The main amendments in H.R. 11581 that relate to proper controls over the release of new drugs appear to be as follows:

1. Greater procedural flexibility for the Secretary of Health, Education, and Welfare in acting on new drug applications;

2. A requirement that new drug applicants keep records and furnish reports on experience with new drugs both in the investigational stage and after approval for the general prescription market;

3. Strengthened authority for the Secretary to remove approved drugs immediately from the market if they present an imminent hazard to the public health.

We believe these amendments are fully justified. We are not prepared to comment on the specific language in which they are drawn, but we hope that they will have the effect of freeing the Food and Drug Administration from undue pressure in approving applications and of enabling the agency to make a thorough evaluation of the evidence in behalf of each new drug. We fully subscribe to the need for

a reporting system on experience with new drugs and to the proposal to enable the agency to withdraw unsafe drugs promptly from the market.

We suggest further that the new regulations recently announced by the Secretary of Health, Education, and Welfare, relating to the investigational distribution of drugs, be fully reviewed by this committee for possible additional legislative authority that may be needed to make them effective. We understand, for example, that there is some question as to whether the Food and Drug Administration has authority to require animal tests before a drug is tried out on human beings. We think that such animal testing should be required and that the Food and Drug Administration should clearly have whatever authority it needs to enforce such a requirement as well as other requirements relating to clinical testing.

Several other amendments in H.R. 11581 also bear significantly on the safety and effectiveness of drugs for human use. These amendments include the following:

(1) Authority for the Secretary of Health, Education, and Welfare to issue regulations establishing standards for manufacturing procedures and controls;
(2) Clarification and strengthening of factory inspection authority;
(3) Requirement that drugs be pretested for efficacy;
(4) Certification of all antibiotics;
(5) Requirements for truthful statements in advertising;
(6) Special controls for barbiturate and stimulant drugs.

In general we support these amendments and have only a few general observations to make on them.

1. MANUFACTURING STANDARDS

We believe that the authority for establishing standards for manufacturing procedures and quality should be strengthened by a provision for licensing drug manufacturing establishments.

2. FACTORY INSPECTION

We understand that the proposed factory inspection amendments, which would apply to all establishments under the Food and Drug Act, have been criticized as giving overly broad and vague authority for inspection. We think that the authority should be broad enough to allow for adequate inspections, but that it would be wise to make the authority appropriately specific, so that it will stand up in court if challenged.

3. EFFICACY TESTS

We strongly support the proposal that new drugs be pretested for efficacy in addition to meeting existing tests for safety. In effect, this will mean that the manufacturer must back up his claims as to what the drug will do. This is an essential measure to protect the user of medicines against wasting his money and delaying adequate treatment of his illness. Ineffective drugs are worse than useless; they are actually dangerous.

It is important that the self-dosage, "over the counter drugs," should be covered, as well as prescription drugs, and we support provisions

of the bill that would do so. These provisions should deal a virtual deathblow to the vicious quack medicine industry which robs the American public of hundreds of millions of dollars a year. The ordinary person is in no position to evaluate such claims, and many are easily led by distress to "try anything," no matter how fantastic. Our Government is nearly helpless in its battle to stamp out this dangerous thievery. We cannot emphasize too strongly the need for these provisions.

As we understand it, however, efficacy will have to be shown only if the drug is introduced or a new claim is made for it after the enactment of the law. This leaves many worthless drugs now on the market subject only to the much weaker controls of the present law which puts the burden of proof on the Food and Drug Administration in a court of law to establish that a drug is not effective. We think the Food and Drug Administration should be allowed to challenge the efficacy of an existing drug under the new suspension and withdrawal procedures and to require proof of efficacy to be shown, at such time. Possibly this is contemplated by the language of the effective dates section, but it is not clear, and we think it should be made clear. Otherwise, it may be many years before we have a genuinely effective law that will actually keep worthless drugs off the market.

4. CERTIFICATION OF ANTIBIOTICS

We support the proposed provision giving the Secretary power to require certification of batches of all antibiotics in addition to the five antibiotics presently listed in the law. As we understand it, many of the newer antibiotics stand in greater need of the certification procedure than the ones already covered by the law, some of which, in fact, might safely be decertified. Omission of the newer antibiotics, however, is a loophole which should be closed.

The provisions relating to records and reports on antibiotics parallel the proposed amendments relating to records and reports on experience with new drugs and should be enacted for the same reasons.

5. ADVERTISING

The need for legislation to control drug advertising grows to some degree out of the breakdown of the machinery for voluntary policing of such advertising, which at one time was exercised by the American Medical Association. Prior to 1955, drug advertisements in the Journal of the American Medical Association were scrutinized for accuracy by the association's drug council. In 1955, however, a change in policy took place and supervision of advertising in the Journal was taken over by an advertising committee. The result was a tremendous increase in drug advertising in the Journal and other professional publications which followed the lead of the Journal. There also resulted a complete breakdown in the system of voluntary controls over drug advertising theretofore relied upon by the American Medical Association and the medical profession generally to make sure that such advertising was fair and truthful.

We strongly favor appropriate measures to enforce truth in advertising by the drug industry. We have been greatly impressed with the harm done by costly and misleading advertising by the drug indus-

try. Here, we have a real safety issue. Essentially the problem boils down to (1) concealment of dangerous side effects of certain powerful drug agents, and (2) exaggereated or unfounded claims for effectiveness of the drug.

The AFL–CIO takes the position that doctors should receive copies of drug package inserts along with promotional material mailed to them. In the case of new drugs, doctors should get a full statement of all relevant findings required to be made under the new drug section of the Food, Drug and Cosmetics Act. We understand that regulations to this effect have been issued by the Food and Drug Administration, but the requirement should also be written into the law.

We believe drug advertisements should include a proper warning as to side effects, accomplished in whatever way is most feasible, under the supervision of the Department of Health, Education, and Welfare, and a full and accurate statement of the efficacy of advertised drugs.

These measures should do much to remedy the low estate into which prescription drug advertising has fallen and to increase the protection of the public against errors inadvertently made by doctors on the basis of inadequate information. In view of the intense personal stake that any sick patient has in the matter, the general public has the right to demand that information going to doctors be truthful and complete. We cannot be satisfied with anything less.

Under H.R. 11581, the advertising amendments would be administered by the Federal Trade Commission through a broadening of its present authority for policing misleading advertising. We think your committee should give serious consideration to transferring this authority, insofar as drugs are concerned, to the Food and Drug Administration, as the more appropriate agency for this purpose.

We have no special comments on the proposed controls for barbiturate and stimulant drugs other than to express our general position in favor of such controls. We note, however, that while stimulant drugs are quite broadly covered, the sedative drugs are limited to barbiturates. We believe that controls over sedative drugs should be of similarly broad character, in order to prevent the bootleg market from simply shifting over from barbiturates to some other type of sedative.

Mr. Chairman, I would like to say, in behalf of our organization, that we hope the present Congress will move rapidly to enact necessary legislation on drugs, which in our view includes price reform as well as health and safety measures. The drug issue has been in the forefront of public concern for over 2½ years, and rightly so. There are those who may urge that legislation not be passed in the present atmosphere of an aroused public concern in the wake of the disclosures as to the tragic effects of the drug thalidomide. But I suggest that that opinion will be even more aroused if nothing is done or if token, halfway measures are adopted. The usual atmosphere in which food and drug measures come under consideration is monumental public apathy, and perhaps the present interest seems remarkable only by contrast.

The drug issue has been exhaustively explored. The passage of time and the occurrence of new incidents serve only to confirm the

need for action. We hope that action will be taken promptly. It would be cruel and inhuman to delay this action any longer.

Thank you, Mr. Chairman, for the opportunity to be heard.

The CHAIRMAN. Thank you, Mr. Biemiller, for your statement on behalf of the AFL–CIO.

I do not know if you are aware of it or not, but these hearings developed a fact which many are aware of. There seems to be a great deal of emphasis placed on the unfortunate incident of thalidomide, and it was pointed out here a couple of days ago that under present law this situation could have been adequately dealt with.

Now, no one has pointed out anything in the proposed amendments how the arm of the Federal Government would be strengthened insofar as that unfortunate experience is concerned.

So I think that at these hearings we must keep in mind what the actual problem is in dealing with it.

I agree that the tragic and unfortunate incident of the worldwide publicity and particularly the results in Europe from the use of thalidomide has emphasized the general need for strengthening our food and drug laws. I think also we should keep in mind that because of this highly publicized incident, it appears that it is not affected by this bill at all.

Mr. BIEMILLER. Quite obviously, Mr. Chairman, the law in this instance did keep the drug off the market, but it kept it off the market because Dr. Kelsey simply refused to cave in under the pressures exerted.

The CHAIRMAN. Because the agency and the ones responsible in the agency did not approve it.

Mr. BIEMILLER. That is correct.

Mr. DINGELL. As a matter of fact, Mr. Chairman, I understand that the history of this is simply that Dr. Kelsey was able to keep thalidomide off the market solely by technicality, and that is by sending back for additional information and by failing to approve the claim, and that she actually had no basis other than her suspicions which required her to keep sending the application back for additional information.

And it was only by this technicality that she was able to prevent certification of this drug.

The CHAIRMAN. The gentleman is rather familiar with the provisions of law with respect to foods and drugs, as has been demonstrated during the course of these and many other hearings.

But everyone knows, if the Food and Drug Administration had failed to prove it, they could have gone to hearing on the subject.

I just point that out. I do not think we should go into something that is foreign to this particular emotional problem to settle some other question.

Mr. Roberts?

Mr. ROBERTS. Mr. Biemiller, I agree with you on this matter of truth in advertising.

I am not too sure that I agree with you that this authority ought to be transferred. It would seem to me that the Federal Trade Commission has the authority—perhaps they are not using it.

Mr. BIEMILLER. There have been a couple of cases in recent years, as you know, Congressman; Doan's pills, if I remember correctly, is a

case that went through several years of litigation before an order was finally issued.

You may be correct, and this is certainly not a major point that we would be stressing.

What is in the back of our minds is the fact that an awful lot of technical information is needed in judging the truth in advertising in this area.

I would agree that if the Federal Trade Commission was functioning in a determined manner, it could draw upon the knowledge of FDA. We simply throw out a suggestion that it might be preferable to let an agency that is expert in the drug field—the specific field of efficacy and the other problems relating to drugs and the side effects that have been developed—pass judgment rather than one that is primarily expert in the advertising field.

Mr. ROBERTS. I observe some of the TV advertising and it seems to me that they make very great claims as to the cure and relief of certain matters that I have certainly a lot of concern about as to one of the products that is being advertised, because I happen to know it is a new field, and it is a field where, in taking the wrong thing, it can irreparably damage the person who takes it.

I certainly agree with you that whether we put anything in this bill or whether we simply stress in the report that attention should be given to this matter and perhaps the two agencies could very well work together, one supply the technical information and the other supply support where it is needed, but I certainly agree with you that there is a dangerous situation in that field.

Now, to go back to your statement as to over-the-counter drugs, I am one interested in what we can do about items such as aspirin, turpentine, Vick's salve, and a lot of these things that I suppose may not effect a cure, but perhaps they do afford some type of relief.

I am wondering if there is very much we could do.

Now, if we were to require prescriptions for this type of item, we are simply driving the price very high. There are some types of maladies or discomforts that aspirin does relieve.

Mr. BIEMILLER. That is right.

Mr. ROBERTS. And that are used many times by people without the services of a physician.

I am wondering if you do not think we ought to leave that as is.

Mr. BIEMILLER. Well, let me raise a question there. Certainly I would agree that most of the aspirin advertising generally adds that if a headache persists, you should see your physician, and so on, which is all to the good.

But it happened that within the last week or so I took a couple of pills of a so-called superaspirin—I will not name it because it would not be fair. I mentioned this to my doctor, whom I visited only yesterday on a couple of matters, and he said: "You should not be taking that. That is going to have an adverse effect on you."

Now, this is another preparation that is sold right over the counter. You can buy it in any drugstore in America.

I just raise this as the kind of thing that bothers us. I am not saying that it is an easy, simple problem. I know what is bothering you.

I have, in one way or another, been connected with attempts to pass legislation in this field for about 25 years, and I am reasonably familiar with the problems involved.

But this is what bothers us. I am sure you are aware of the absolutely worthless medicines that have been, and in some cases are still being, sold. I remember in my youth a preparation that was sold rather widely and became a quite desirable medicine during prohibition days called Peruna, which was prune juice and alcohol. It probably did not do anybody harm, but it did not do them any good, except that it was a way of getting a little alcohol during prohibition days.

This is the kind of problem that concerns us here, and I think that at a minimum the proprietaries ought to be required to show the efficacy of their drugs before being allowed to proceed as widely as they have been.

I mean, in the case of aspirin you have proven facts that for certain kinds of things aspirin is very valuable. Of course, if we got into the price of aspirin, I might have something to say on that, but I realize that is not a subject before this committee.

Mr. Chairman, may I say, parenthetically, that I am sure you understand our attitude on this. We are expressing our concern about the high prices of many drugs, but we realize that this committee cannot have a direct effect upon that problem.

Mr. ROBERTS. I appreciate your statement, Mr. Biemiller.

Mr. Chairman, that is all I have.

The CHAIRMAN. Mr. Schenck?

Mr. SCHENCK. Thank you, Mr. Chairman.

I have been very deeply interested in Mr. Biemiller's statement, because I know he has had such a longtime interest and close connection with this problem.

Now, on the first page of your statement, Mr. Biemiller, you say:

> Here we have an industry that tried its utmost to bulldoze a dedicated Government employee into giving a clearance on a drug that the employee suspected was dangerous.

Do you feel that it is fair to indict the whole industry? I mean in your own field of labor relations, would you want to indict the entire labor field because of some action by a given group?

Mr. BIEMILLER. I think possibly your point is well taken, and if we had said the pressure came from one drug company, it would have been a more accurate statement.

I have in mind, as I am sure you know, Congressman, the long factual statement put into the Congressional Record by Senator Kefauver of the attempts to pry this drug loose which Dr. Kelsey resisted.

I think your criticism has merit, and you are right: that we probably should have referred to the company rather than to the industry as a whole, although I think you will find other instances that have not been made public in the way that the thalidomide situation has been.

Mr. SCHENCK. I appreciate that statement.

Now, Mr. Biemiller, speaking only for myself, as a member of this committee, I am deeply desirous that safer drugs, medicine, and medi-

cal preparations are made available to everyone who needs such help, at a price that they can afford to pay, and from which they have every right to expect they will receive this help.

So we here in our hearings this week have been trying to develop the necessary information on which to make a legislative judgment.

Now, I am sure you know, for example, the Eli Lilly Co., which is highly regarded as a pharmaceutical manufacturer. Its President, Mr. Beesley, testified that they would this year spend from $20 to $21 million in research alone, and in further questioning Mr. Beesley, I asked him if the improved manufacturing methods which they developed through their research and so on, if this is not also reflected in a lower price of their products, and he said very definitely it is; that they have had a considerable number of downward revisions in prices.

He mentioned one drug that I mentioned to him, the drug insulin, which has been extremely important to many, many people.

Mr. Beesley and the Eli Lilly Co. manufacture that drug, have been one of the leading manufacturers of that drug.

He said this: That in about 40 years, since they first introduced insulin—

> We have had 13 price reductions during that period and that the current price is about 6 percent of the price that prevailed in 1922.

Now, I would think that this indicates that the industry is trying to bring the costs down even though they have got to recapture their research costs, would you not agree?

Mr. BIEMILLER. Certainly they have to recapture their research costs, but the fact does remain—and I think the evidence has been produced—that this industry, as an industry, is still showing the highest return of any industry.

There have been specific cases shown of drug prices that have not dropped to any appreciable extent.

You were referring, of course, just a moment ago, to a drug that has been on the market for a good length of time, as to which it has been possible to learn new methods of mass production.

I realize that our concern with the high price of drugs is a problem that this committee itself cannot handle; I am fully aware of this because of my experience as a member of this committee and my knowledge of the care that members have always exercised in these matters. I believe this committee is doing its best to find a solution to the drug problem; hence, I regret you cannot really attack this price question.

I think that you will find, if you look into it on your own, from the evidence that you can pick up from the Kefauver hearings, from just good, basic, standard reporting services like Standard & Poor's, that the industry as a whole is still getting the highest return of any industry in the country. This is something that I think you ought to take into consideration.

Now, if cross-licensing, which the Kefauver original proposal called for and which the Celler bill calls for, were provided for, I think we could immediately drop the prices of some of these drugs.

Mr. SCHENCK. I appreciate the gentleman's point of view on that.

We had a gentleman here, a professor in business administration, who tried to draw some parallels between what has happened in this

country, for example, and what is happening in Russia, and apparently there is a pretty strict control and planned economy in Russia.

We have also had other witnesses who stated unequivocably that the advanced and scientific medical treatment, the kind of drugs and so on that we have developed and are receiving in this country is far superior to any other country in the world.

It would seem to me that our committee must do everything it can to insure safety and effectiveness of drugs, ample drug laws, inspections and all that, to protect the public interest and health and we are already receiving in this country the very best medical attention and drugs of anywhere in the world, and life has been prolonged quite a span as a result of many of these discoveries.

So we must also, somehow or other, leave enough leeway here to encourage research and encourage incentive and encourage an opportunity to develop new drugs and new methods and new medical ways of doing things.

Now, again, we had Mr. George Cain, who is president of the Abbott Laboratories in north Chicago, and Mr. Cain testified, I believe, that his company will spend some $11 million in research this year, and that their advertising budget for this year is about $2,275,000.

So it would seem to me that they are not going clear overboard in their advertising.

I wonder if you cared to comment on that, Mr. Biemiller, because you indicated in your statement you thought a disproportionate amount is being used in advertising.

Mr. BIEMILLER. This is still our opinion.

On the research question, certainly we want research done.

I would just like to point out, however, that some of the most important drugs of modern times have not come out of the research done by the drug companies: they have been financed by funds supplied either by the Government or by public subscription, the various foundation type of operations. I hate to think what the prices charged for some of the drugs that have come out of governmental or foundation research would have been if they had been developed by private industry.

You have to weigh all of these matters, I think, one against the other.

Mr. SCHENCK. Mr. Biemiller, I could not agree with you more as to the outstanding scientific contributions made by National Institutes of Health and other portions of the Public Health Service. They have contributed tremendously to the knowledge, growth, and ability of the science of medicine and the treatment of people who are ill.

We have a chart here presented to us by the Proprietary Association, which states the source of the information is the U.S. Bureau of Labor Statistics. This chart shows that between 1940 and 1960 packaged medications have gone up 30 percent; housing has gone up 72 percent; services, 111 percent; foods, 150 percent; wearing apparel, 166 percent.

So, on the basis of that information from the Bureau of Labor Statistics, it would seem that the drug industry as a whole is making a rather good comparison with other living costs, would you not agree?

Mr. BIEMILLER. May I ask our economist to comment on this matter?

Mr. SCHENCK. Surely.

Miss DRAPER. I have not been studying particularly the prices of proprietary drugs: I have been more concerned about the prices of prescription drugs. I think however, you would have to take into account the level from which the prices start.

In other words, you have the situation where prices fail to fall when they ought to. Maybe they do not go up much, but they are very high to begin with. It is a little misleading to rely wholly on the percentage of increase over a given period, unless you take into account the level at which the prices start and whether those prices may be unreasonable in themselves.

I think this was the point that was made in the case of prescription drugs. You have an enormous spread between cost and price, and the price does not drop; maybe the price does not go up either, but it would not be altogether a disproof of excessive prices to use this type of chart.

Mr. SCHENCK. Miss Draper, I think you have a very definite point there, but, again, and I am not defending any exorbitant price that is charged for any drug by any manufacturer, I think these safe and effective drugs ought to be made available to people who need them at a price they can afford to pay.

My doctor recently told me, for example, that he could prescribe a drug which would be expensive in a given instance, but which would save a 4-week, ordinarily 4-week, stint in the hospital and consequent loss of time from work.

So, while the price of the drug may seem to have been high, the overall cost of health may have been reduced by the use of that drug.

Mr. Biemiller, you dwelled at some length on advertising, and that is one that concerns me also a good bit because of the question of printing all of the so-called contraindications and side effects and so on in medical journal advertising or any other type of advertising.

The testimony we have received here from the pharmaceutical manufacturers is to the effect that the doctors are given full information by extensive brochures on the medicine that is being proposed, the compound, and I think you also indicated, Mr. Biemiller, that sometimes one compound will react one way on one person, and the same compound will react another way on another.

Therefore, it is a medical judgment of the doctor as to whether he should use X, Y, or Z brand, where perhaps the same active ingredient in the compound, with perhaps different inert material, binding material, or whatever you might want to call it, is in there and this may affect individuals differently.

What is your feeling on that?

Do you still think that they ought to publish all of these contraindications and the side effects and so on in all the medical journals?

Do you think that would be in the public interest?

Mr. BIEMILLER. May I again call on Miss Draper, who has been researching this matter rather thoroughly.

Miss DRAPER. I do not know that we would want to testify as to exactly what should appear in a drug advertisement.

We would think that the Food and Drug Administration should work this out in some practical manner.

I think that, in substance, what is proposed is to have proper warnings in advertisements, as to side effects and contraindications.

We would certainly want them in there if it is at all feasible and practical.

It is a matter of working out, it seems to us, exactly how you do it.

Mr. SCHENCK. I appreciate that.

I just want to point out, and I hold them in my hand, for instance, these are printed exhibits which were given to the committee for the committee record. These are reported to be—these booklets are provided by Abbott, for example—these are purported to contain complete information for the doctor, scientific information, showing all of the side effects, the dosages, and the chemical makeup and molecular construction and everything else of these various remedies.

It is my understanding that all of the pharmaceutical companies do this same procedure with the doctor prior to the so-called detail man or salesman calling on the doctor.

Do you feel that this is a sufficient type of information, or do you think this or additional information ought to be included as a full-page-or-more ad?

For instance, I saw yesterday in a doctor's book two-thirds of a page on one drug in order to describe that drug.

Now, should that be included in advertising?

Mr. DRAPER. I guess the problem is that an advertisement generally just stresses how good the drug is and so forth and so on without any warnings at all, and it would be a matter of some practical method of getting across due cautions.

Some of these descriptions of drug effects, and so forth, I understand, run to 40 pages, and this is obviously not practicable.

We think there should be an offset, shall we say, to the psychological effect of an advertisement that is all about a whiz-bang new drug, but which gives no inkling as to cautions to be observed.

You might win somebody over with an advertisement so thoroughly that he will not look at the brochures quite the way he ought to.

Mr. SCHENCK. I can well appreciate that position, Miss Draper, because my mother, bless her heart, would listen to the radio programs and read newspaper advertisements and say, "Now, that sounds exactly like I feel and that is what I ought to get."

So I know that that is very important.

Mr. Chairman, I think Mr. Biemiller and his associates have made a very fine contribution to these hearings.

The question of using generic or chemical names on drugs is quite a difficult problem for the reason that many generic and chemical names are very long and involved, and also the packages are relatively small, and there is some question whether or not an abbreviation of some sort that is agreed upon in the medical profession would not do just as well.

And there is some question in the minds of many of us as to whether or not that would actually produce a lower cost in the drug.

Now, do you have any evidence to the contrary, Mr. Biemiller?

I have read Senator Kefauver's statements and have followed that quite closely.

Mr. BIEMILLER. In the semitherapeutic field, for example, I have recently run into a situation where a rather high-powered vitamin, in

exactly the same structure, is advertised under three different names and at three different prices. All three products consist of exactly the same compound.

Now, the question is—each one has a name, X, Y, Z—if the doctor prescribes X, which is the most expensive one, it is pure happenstance if the person finds out he can get exactly the same thing as Y or Z, which are much cheaper.

This is the kind of thing that is bothering us here, sir.

Mr. SCHENCK. Mr. Biemiller, how would you reach, legislatively, the problem of asking the doctor to prescribe any certain drug?

The doctor does not get a commission, I do not believe, does he?

Mr. BIEMILLER. I hope not, not if he is an ethical doctor, and I think most doctors, practically every doctor, is an ethical doctor.

Mr. SCHENCK. I would think so.

A doctor, as I understand it in my discussions with some of them, has developed a certain degree of confidence, faith, and assurance with a given company because of his acquaintance with the quality control and scientific ability of that company, and so they gravitate to the idea of prescribing X-named drug.

Perhaps you buy an Arrow shirt instead of another shirt, and perhaps the other shirt is made exactly the same with a different label on it.

How would you get at that, legislatively, to require the doctor to say: "I want this or that"?

Miss DRAPER. I do not think you could require the doctor to do this.

I think that if this bill is enacted, the doctor might feel safer in prescribing by generic name. Many doctors are conscientious about taking their patient's pocketbook into account, if they can, and this bill would certainly make it easier for them to do so.

You would have a much more uniform quality of drugs assured, with efficacy assured and procedural controls established over manufacturing operations all of which are provided by this bill.

So I think the bill would encourage more general usage of generic names.

I do not think you would cure the problem entirely, sir.

Mr. SCHENCK. Just this one question, Mr. Chairman.

There would be nothing for the doctor to use the generic name and right after it say Abbott, Parke Davis, what have you, would there?

Miss DRAPER. If he felt strongly about it, I suppose he could still do so; yes.

Mr. SCHENCK. That is all, Mr. Chairman.

Thank you very much, and thank you, Mr. Biemiller and Miss Draper, for your fine help.

The CHAIRMAN. Of course, the problem there is that the doctor writes in a way that nobody can read it anyway.

Mr. SCHENCK. May I just make a little comment there. A friend that I met yesterday thought that we should develop a regulation requiring doctors to make typewritten prescriptions.

Mr. DINGELL. Or teach them to write.

The CHAIRMAN. Sometimes you do not know whether that is the reason or whether they are using Latin terms or Greek terms, and then,

of course, if you get into that field, everybody has to take Latin or Greek.

Mr. Friedel?

Mr. FRIEDEL. Mr. Chairman, I listened to every word Mr. Biemiller said in his statement, and I was very much impressed.

I am not going to get into the price end of it because another committee has that jurisdiction, but I am impressed about this statement on page 3:

> The safety of drugs is paramount, and every effort should be made to see that unsafe new drugs do not reach the public, and fully adequate animal tests should be required.

I hope the committee will pursue that further. Before any experimental drug is marketed, that it will have been adequately tested on animals, and that when experimental drugs are used on humans, they will get permission from the patient before they are used.

It can be done in a lot of ways.

I imagine the doctor can say:

"I have tried everything else, and it has not worked. There is a new experimental drug that might help. I would like to have your permission before I give you this drug."

I hope that will be included in this bill.

You have been very patient, but it is 12:30, so I will cut my statement short by saying that I wholeheartedly agree with that part of your statement.

Mr. BIEMILLER. Thank you, Congressman.

The CHAIRMAN. Mr. Thomson?

Mr. THOMSON. Mr. Chairman, I would like to ask Mr. Biemiller a question that I think is related to this price problem.

You have said very little really can be done, however, to bring down drug prices unless action is taken to deal with the patent monopolies which have been estimated to encompass about two-thirds of the prescription drugs on the market.

Now, this committee has before it and will consider next week at this time a bill known as the quality stabilization bill, which will deal directly with the price that is paid for drug products as well as others.

I would like to inquire whether you appeared before the subcommittee of this committee either for or against the quality stabilization bill.

Mr. BIEMILLER. The AFL–CIO is opposed to the quality stabilization bill.

Mr. THOMSON. You think that bill should not be enacted?

Mr. BIEMILLER. This has been a longstanding position of the labor movement.

Mr. THOMSON. Could you prepare a set of standards that would be used or might be suggested to determine the term "efficacy" or "efficacious"?

Mr. BIEMILLER. We think that the Food and Drug Administration could do so.

Mr. THOMSON. You have none to suggest yourself?

Mr. BIEMILLER. I would not presume, as a layman in this field, to try to lay out standards or definitions in this area.

I know what the phrase means to me as a layman, but that is an entirely different matter than the point you are raising.

Mr. THOMSON. Is it not the problem that it means something different to everybody?

Mr. BIEMILLER. But I think somewhere there has to be a standard created, and I think the Food and Drug Administration would be the proper agency to do that.

Mr. THOMSON. You would like to have them determine whether a drug is efficacious or whether it is not?

Mr. BIEMILLER. Quite so.

Mr. THOMSON. Did you read all the advertising on those pills you took the other day?

Mr. BIEMILLER. Yes.

Mr. THOMSON. You did?

Mr. BIEMILLER. I did.

The CHAIRMAN. Is that the reason you took them?

Mr. BIEMILLER. No.

I took them, Mr. Chairman, on the same basis that so many people take pills. Somebody said, "This will take care of the bad headache you have got."

I had a sinus headache, and I pray you do not have them, but if you do, you know you feel the top of your head is going to blow off.

I have a prescription drug for this problem which I, unfortunately, had left in Washington. I was in Chicago when this happened.

I read the advertising. All the advertising said was it was better than aspirin, as a practical matter; the advertisement was a little longer than that, but that was the basic statement on the little box.

Mr. THOMSON. I have no further questions, Mr. Chairman.

It disturbed me to hear in the testimony this morning that Mr. Biemiller was still, after all of these many years, in the need of some pills occasionally.

I have known him for a long time, and I had hoped that he had outgrown this need.

Mr. BIEMILLER. Unfortunately, Mr. Chairman, I am afraid statistics show that the older we get, the more likely we are to have to take pills.

The CHAIRMAN. You mean the more likely we are to come to a full realization in our own minds that a pill will do us good.

I thought Mr. Schenck would ask you further about the information presented by one of the witnesses with reference to prices, since you did get into that, and which interested me.

It showed how prices rose from 1940 to 1960, packaged medications up 30 percent; housing up 72 percent; all goods and services up 111 percent; foods up 150 percent.

Do you agree with that?

Miss DRAPER. We have no way of disputing the figures at this point.

I think we did respond on this point. I said that I did not know about the proprietary medicines.

The CHAIRMAN. On behalf of the committee let me thank each of you for your appearance here and the contribution you have made to this hearing.

Mr. BIEMILLER. Thank you, Mr. Chairman.

We appreciate the opportunity to appear.

The CHAIRMAN. Our [illegible] colleague, Harry L. Towe, advised me that he will be unable to be here tomorrow, when he is scheduled to appear. He would like to include a statement in the record.

STATEMENT OF HARRY L. TOWE, GENERAL COUNSEL, MEDICAL ECONOMICS, INC.

Mr. TOWE. Yes, Mr. Chairman.

It is a statement of Mr. William L. Chapman, Jr., who is the chairman of the board of Medical Economics, Inc., publishers of medical journals and books. I would appreciate having permission to insert that statement in the record.

The CHAIRMAN. Very well, we will be glad to receive it. It may be included in the record at this point.

(The statement referred to is as follows:)

STATEMENT OF WILLIAM L. CHAPMAN, JR., ON SECTION 131 OF H.R. 11581

My name is William L. Chapman, Jr., I am chairman of the board of Medical Economics, Inc., publishers of the following medical publications:

Medical Economics: A medical journal which circulates to all active practicing physicians and osteopaths in the United States. This is a biweekly journal which has been published for 39 years and the circulation is approximately 193,000.

Physicians' Desk Reference: An annual reference book with quarterly supplements which makes available essential prescription information on major pharmaceutical properties, biologicals, and antibiotics in convenient reference form, and has been published for 16 years. The 1962 edition of "Physicians' Desk Reference" has the following approximate distribution and circulation:

MD's and DO's in active private practice	192,000
MD's in U.S military hospitals (U.S. and abroad)	7,000
Hospitals	23,000
Residents and interns	42,000
Senior medical students	7,200
Druggists	14,000
Miscellaneous (including Federal and State food and drug officials, State health officers, medical and pharmacy schools, nurses, dentists, industrial clinics, hospital staff physicians, pharmaceutical manufacturers, and foreign)	74,800
Total	360,000

Riss: A monthly medical journal circulating to over 51,000 residents, interns, and senior medical students.

RN: A monthly journal circulating on a subscription basis to approximately 165,000 registered nurses in active practice throughout the United States.

On behalf of "Medical Economics" and its affiliated publications I would like to present our position on Section 131 of H.R 11581.

This section proposes to amend the Federal Trade Commission Act to require that all advertisements of prescription drugs contain a conspicuous, full, and accurate statement of the efficacy of the drug, as well as a conspicuous and truthful disclosure of the drug's formula, side effects, and contraindications. In addition, section 131 authorizes and directs the Federal Trade Commission to prescribe such rules and regulations as may be necessary to administer the new provisions.

A fair conclusion to be drawn from the proposals in section 131 is that the sponsors of the legislation are under the impression that physicians in prescribing for their patients rely almost entirely upon information provided in medical journal advertisements. This is an inaccurate assumption.

While all of us will agree that before a physician prescribes any drug he should have as much information as is available including the composition, action and uses, administration and dosage, the side effects and precautions, and the contraindications, it should be emphasized that this information is provided to the physician in many different ways other than through journal advertising.

The physician received a wide range of information directly and indirectly from the pharmaceutical manufacturer which enables him to intelligently prescribe a drug. In addition to that source of information, there are over 400 medical journals published in the United States for approximately 235,000

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physicians. These publications range from the small county medical bulletins and specialty journals to the larger therapeutic publications. The vast majority of medical journals are supported mainly by advertising of pharmaceutical products and a large portion of this income is used to support editorial staffs which either prepare original therapeutic, scientific articles, or review and publish submitted material from clinical researchers. These articles are of great value to the practicing physician in bringing to his attention the latest developments in drug therapy.

In addition to the information provided by the manufacturer and the information contained in therapeutic articles published in medical journals, the physician has available to him many sources of accurate information with respect to the specific use of prescription drugs. Among the recognized drug directories which surveys show are in constant use and relied upon by active practitioners are "Merck Manual," "Physicians' Desk Reference" and "New Modern Drug Encyclopedia." These reference books substantially provide detailed information which section 131 proposes should be included in all journal advertising and these books are available to all physicians and are actually used by a very high percentage of practicing physicians throughout the United States.

As a result of our experience as publishers of medical journals, we are certain that the purpose and function of advertising prescription drugs in medical journals are as follows:

(1) To announce the availability of a new drug indicating the disease or diseases for which the company has been given Federal Food and Drug Administration approval to market the drug;

(2) To inform physicians of any additional usages of a drug discovered after the product has been on the market for some time;

(3) To remind physicians of the availability and merits of a drug about which they already possess detailed written information. Thus, the primary function of medical journal advertising is designed to announce, to inform, and to remind.

We should like to emphasize that we agree fully with the view that before a physician prescribes a drug, he should have all of the information which he needs readily available to him. We think, however, that after the committee has fully explored the subject, it should conclude that medical journal advertising is not the proper medium through which to attempt to provide this information, and we think that the committee can also conclude that all of the information which section 131 requires to be in journal advertising is now readily available to all physicians through the various other media which we have referred to in this statement.

In the final analysis, the physician is the one who prescribes and the one upon whom a patient relies, and we are firmly of the opinion that the physician discharges his obligation to properly inform himself before prescribing for a patient.

We are opposed to the proposals contained in section 131 because we do not think they are necessary nor do we think that they will actually serve their intended purpose. We think, however, that the present law could be amended to require all advertising of prescription drugs to include a statement advising the physician that "Before prescribing you should secure full and complete information by referring either to the manufacturer's literature, the officially approved product brochure, or package insert."

Mr. TOWE. I would also like, if I may, to make available for the committee files a publication of ours which is known as "Physicians' Desk Reference," which is in the hands of every practicing physician in this country and also circulates to hospitals and others. It is referred to in the statement.

It is a book that contains over 2,000 descriptions of pharmaceutical products, those which must be obtained through prescription, and is of great value to physicians.

It might be of some help to the committee determining whether or not, on this question of advertising, complete information is presently in the hands of doctors.

If I may make that available as a part of the committee's files, not the record.

The CHAIRMAN. We will be glad to receive it for the files for information of the committee.

Mr. TOWE. Thank you, sir.

The CHAIRMAN. A few days ago I received a communication from our colleague, Mr. Bolling, of Missouri, who brought to the attention of the committee the statement from Dr. Rudolph Seiden, vice president of Pharmaceutical Research and Control, Haver-Lockhart Laboratories in Kansas City.

I would like for the statement to be included in the record at this point and for a copy of it to be forwarded to the Secretary of HEW with the request that he give us his comments on it at an early date.

(The documents referred to follow:)

PROPOSED AMENDMENT TO THE FOOD, DRUG, AND COSMETIC ACT'S NDA SECTION 505

"From the provisions of section 505(a) are exempted compounders of drugs, provided the manufacturer of a basic drug possesses an effective NDA which includes formulations of this drug such as tablets, solutions, ointments, or powders, plain or mixed with other drugs.

"The manufacturer is obligated to sell the basic raw material only to drug compounders who are equipped to follow all requirements of production, control, and labeling contained in the NDA with respect to the various dosage forms.

"The NDA holder and his customers, who must sign an agreement stating that they will observe the requirements stipulated by the FDA, are both responsible for observing them."

Such an amendment would (1) save the FDA many thousands of working hours a year by making it unnecessary for it to repeatedly review NDA's or supplemental NDA's for the very same drug; (2) save industry the often high cost of (repetitiously) gathering data needed for an NDA and avoid the sometimes tremendous loss of time necessary to clear an NDA; and (3) make it possible that the public obtains better, newer drugs faster and at lower prices since the compounder would be able to omit from his cost calculations the often high expenses for obtaining an NDA.

Even if, in addition, a public rulemaking procedure would have to be devised that would give the FDA authority to prescribe manufacturing standards and labeling for the finished products—similar to the like regulations concerning antibiotics and (particularly veterinary) insecticides and disinfectants, it would still be a great advantage over the current slow procedures which waste time, money, and energy of a multitude of firms compounding the very same (or very similar) drugs.

RUDOLPH SEIDEN, CH. E., D. SC.,
HAVER-LOCKHART LABORATORIES,
Vice President, Pharmaceutical Research and Control.

PROPOSAL FOR CHANGE IN NDA PROCEDURES

I am speaking for Haver-Lockhart Laboratories, for 42 years one of the leading manufacturers of veterinary pharmaceuticals and biologics, and for many of my colleagues in this industry when I state that we have found it increasingly difficult throughout recent years to develop new products to be marketed economically. In fact, it often becomes prohibitive for us to spend the amounts of money currently needed for testing new veterinary drug preparations since the cost may run into four and five figures. Thus, progress is being hindered and it becomes more and more probable that effective and safe new drugs will become available sooner in foreign countries than in the United States of America.

Not only the high costs of determining tissue and milk residues in large farm animals are the cause of exhorbitant expenditures, necessary for preparing new drug applications (NDA's), but—even more important—the repetitious testing and (supplemental) NDA submission requested by the FDA from each com-

pounder who intends to use the new, already NDA-approved, drug in the manufacture of an identical pharmaceutical product.

Registration of antibiotic preparations and of insecticides, once approved by the FDA and the USDA, respectively, can be obtained easily from any (legitimate) compounder. Why, then, the great difficulties and great costs and time losses with respect to pharmaceuticals?

No doubt a tremendous saving of money, time, and efforts for both the FDA and industry is possible by changing the NDA regulations so that only the manufacturer of the basic drug (raw materials) has to obtain it. He should be informed by the FDA, once and for all, of any conditions the compounders of pharmaceuticals have to fulfill when they wish to add the item to their lines, be it as is or with minor changes as to color, taste, and maybe in combination with other simple, old-established and compatible drugs or inert materials. If the compounder does not follow through, the basic manufacturer (and NDA holder) has to stop selling the raw material to the offender and the FDA can act in accordance with the provisions of the law.

What does this proposed change amount to?

To give an example, such a change would make it necessary for Merck or Cyanamid or a firm X to supply all the information needed to prove the safety and efficiency of a new basic drug, say the sulfonamide S. The hundreds of large and small (human and veterinary) compounders of pharmaceuticals who may wish to add S tablets to their lines could do so without each one having to first submit lengthy NDA's which require each one of them to undertake much unnecessary experimental work and even more unnecessary paper work. All that these compounders should have to do is to sign a form supplied by X in which they declare that they will follow the FDA's specified provisions concerning label text and production and control procedures. Any major variation the compounders might wish to make in formulations or indications, naturally, would have to be cleared with the FDA; but those who want to bring out a simple S tablet could do so without having to lose months of time waiting for a decision from the FDA.

The saving of time and money by dozens, if not hundreds, of firms would benefit the public which, thus could get new drugs much faster and probably at lower costs, without sacrifice of their safety and efficiency. And the FDA would not be overworked, but would have more time for work other than studying countless supplemental NDA's and exchanging much correspondence with the individual compounders. Most if not all of them are reputable firms; to those few which are not reputable, X would not sell, especially if he is made responsible for the compliance by his customers with the FDA's provisions regarding S.

RUDOLPH SEIDEN, Ch.E., D.Sc.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C., August 27, 1962.

HON. OREN HARRIS,
House of Representatives,
Washington, D.C.

DEAR MR. HARRIS: This is in reply to your letter of August 11, 1962, regarding a proposal of Dr. Rudolph Seiden to change the new drug application procedures.

The present new drug procedures were designed in part to prevent drug residues in man's food. It is well established that the improper use of drugs in food-producing animals may leave hazardous residues in meat, milk, or eggs to be consumed by man.

If there were a change in the new drug provisions with respect to veterinary drugs, the same degree of control would have to be exercised. The same scientific groups in the Food and Drug Administration that now consider requests for approval of the use of drugs in veterinary products—the veterinary medical officers, the medical officers, the pharmacologists, the chemists, and others upon occasion—would need to review the request.

We are continually striving to simplify the administrative procedures involved in handling veterinary new drug applications, and believe we have been making worthwhile improvements.

If Dr. Seiden wishes a relaxation of present substantive requirements for clearing new drugs for safety, we would have to oppose the change. We doubt

that an amendment of the law is needed to permit administrative improvements as the need for them becomes apparent.

With best regards.

Sincerely yours,

JOHN L. HARVEY, *Deputy Commissioner.*

The CHAIRMAN. The committee will recess until 2:15. We have gone longer than we intended, but we will be back at that time.

(Whereupon, at 12:40 p.m., the hearing was recessed, to reconvene at 2:15 p.m., of the same day.)

AFTERNOON SESSION

The CHAIRMAN. The committee will come to order.

The first witness this afternoon will be Dr. Lloyd Miller.

Dr. Miller.

STATEMENT OF LLOYD C. MILLER, DIRECTOR OF REVISION, THE UNITED STATES PHARMACOPEIA

Mr. MILLER. Mr. Chairman and members of the committee, my name is Lloyd C. Miller and I reside in Westchester County, N.Y. My academic training leading to a Ph. D. in 1933 from the University of Rochester has been in biochemistry and in pharmacology. My experience has included 8 years with the headquarters laboratory staff of the Food and Drug Administration, and 9 years in industrial pharmaceutical research.

Since 1950 I have served as director of revision of the U.S. Pharmacopeial Convention, an independent, nonprofit scientific oranization devoted to providing standards of strength and purity for drugs.

A published booklet on our organization giving the officers, the board of trustees, and other pertinent information is available here for the committee's use.

The United States Pharmacopoeia is a book of drug standards, as I have indicated, and it is published at 5-year intervals in bound form, and is actually the main product of our endeavors.

A rather comprehensive statement of the nature and aims of the United States Pharmcopeial Convention, Inc., was presented in 1960 to the Senate Subcommittee on Antitrust and Monopoly. If reference to the record of the hearings of that committee does not suffice for the purposes of this hearing, I should like to ask that the statement that I prepared for that committee be included in this record.

The CHAIRMAN. Let it be included.

(The statement referred to follows:)

STATEMENT OF LLOYD C. MILLER, PH. D., DIRECTOR OF REVISION, THE PHARMACOPOEIA OF THE UNITED STATES OF AMERICA, PREPARED FOR PRESENTATION BEFORE SENATE SUBCOMMITTEE ON ANTITRUST AND MONOPOLY

INTRODUCTION

The United States sets up its standards of quality and purity for drugs in a unique way. In this, a large measure of reliance is placed upon the United States Pharmacopoeia, which is a relatively concise compendium that has appeared regularly at intervals since 1820. The Pharmacopoeia, or U.S.P., as it is commonly called, provides definitions and specifications of strength, quality, and purity for drugs, including the necessary test procedures. It is prepared and published by a private scientific nonprofit institution that exists for the sole

purpose of providing drug standards. The U.S.P. is revised entirely every 5 years, and the latest edition, the 16th revision, appeared in March of this year. Interim revision of the standards is effected by means of supplements.

PURPOSE OF THE PHARMACOPOEIA

The object of a pharmacopoeia was set forth in the preface of the 1820 Pharmacopoeia, and remains the same today. In short, the Pharmacopoeia over the years has provided a list of those therapeutic substances that reflect the best practice and teaching of the healing arts and has endowed them, in published form, with standards of identity, strength, and purity that are creditable and firmly grounded on scientific fact. The fulfilling of this objective ever more completely in successive revisions has steadily increased the service rendered to the public and the health professions.

THE U.S.P. ORGANIZATION

The convention is virtually re-created for each decennial meeting, although the rather unusual title "The United States Pharmacopeial Convention, Inc." The corporation meets regularly every 10 years according to a plan adopted in 1820. The latest meeting, the 15th such decennial session, was held on March 29 and 30, 1960.

The convention is virtually recreated for each decennial meeting, although the organizations entitled to membership remain substantially the same. These include the 79 accredited colleges of medicine, the 76 colleges of pharmacy, 7 agencies of the Federal Government, the State medical and pharmaceutical associations, and 12 national professional associations and societies in the fields of medicine and pharmacy. Thus a total of 277 were entitled to representation in the 1960 meeting held recently; of this number, 194 exercised their franchise by sending delegates.

The proceedings of the 1960 meeting have not been prepared but copies of the printed proceedings of the 1950 meeting are being submitted for the use of the subcommittee.

The delegates are appointed to serve not only for the decennial meeting, which usually last only 2 days, but for the entire 10-year period until the next meeting. The convention confers its authority upon an elected board of trustees and the elected officers of the convention, who function very actively during the 10 years between meetings.

It is scarcely possible to emphasize too much how completely independent the convention is in performing its service to medicine and pharmacy in the interest of the public welfare.

THE BOARD OF TRUSTEES AND THE OFFICERS OF THE CONVENTION

The board of trustees consists of six elected members, two of whom represent medicine and two the field of pharmacy, and the remaining two of whom are elected at large from among the convention delegates. The four officers of the convention, the president, vice president, secretary, and treasurer, likewise elected from and by the convention, all sit with the board of trustees.

The members of the board and the officers have always been outstanding leaders in medicine and pharmacy, distinguished for their statesmanship and public-spirited contributions.

THE U S P. COMMITTEE OF REVISION

At its decennial meetings, the convention, in addition to selecting the board of trustees and the officers for the ensuing decade and in addition to receiving reports on the pharmacopoeial program for the decade just ended, elects a committee of revision comprising 60 experts, 20 from medicine and 40 from pharmacy and the allied sciences. This 1:2 ratio of representation between medicine and pharmacy has its origin in the changing character of the respective roles played by medicine and pharmacy in the first 100 years of the U.S.P.'s existence.

The 60 members of the committee of revision are elected by ballot from 120 nominees, who need not necessarily be delegates to the convention, who are selected to provide every type of skill and knowledge required in the U.S.P. revision program. Thus, the committee includes specialists in anesthesiology, cardiology, surgery, and other branches of medicine, and pharmacists, bacteriologists,

analytical chemists, and other specialists in various branches of the actual practice of pharmacy. The committee is organized into subcommittees, each charged with definite responsibility for some phase of the revision program.

The committee of revision is drawn from the entire breadth of medicine and pharmacy. The members serve as individual experts and not as "representatives" of their respective institutions.

Advisory boards of experts outside the committee of revision may be appointed to consider special policy matters. Similarly, ad hoc panels of special consultants are appointed from time to time for highly technical advice on matters of more restricted interest.

The U.S.P. Committee of Revision is responsible for drafting and revising the Pharmacopoeia, while the U.S.P. board of trustees is mainly concerned with maintaining the legal and financial standing of the Pharmacopoeia. The board has broad jurisdiction over general U.S.P. policy, relationship of the U.S.P. with other scientific and professional organizations, and matters having a bearing on the prestige of the Pharmacopoeia.

THE REVISION PROCESS

It is literally true that the Pharmacopoeia is under continuous revision to keep pace with medical progress. The revision process consists of three phases. The first is concerned mainly with the selection of the drugs to be recognized in the next revision; the second phase deals with developing the appropriate standards of strength, quality, and purity and the tests that they require; and, finally, the third major effort is directed toward processing the manuscript and guiding it through the various stages of printing to ultimate publication in bound form.

Since the value of the Pharmacopoeia lies in large measure in the selective list of drugs that it presents, the first phase of the revision receives most painstaking attention. It is mainly in the hands of the 20 physicians elected to the revision committee, who are assisted by pharmacists fully familiar with the pharmaceutical forms of the drugs under consideration. The resulting list consists of those drugs and their dosage forms that are believed to represent the best practice and teaching of medicine. This selection process continues right up to press time. Obviously, U.S.P. status is not accorded to every new drug developed.

We come now to the second phase. While the selection phase is still proceeding, the U.S.P. subcommittees concerned with drafting the standards begin their work. Proposed or provisional standards are put to actual laboratory test under the supervision of a member of the U.S.P. Committee of Revision and the final standards are set accordingly.

The work of the third phase, that of the actual publication, is shared as widely as possible by distributing proof copy to the entire revision committee and, in addition, to a large number of other scientific and technical experts. The comments thus received are taken into account in settling on the final text. The task of guiding the text through the various stages of printing is handled from U.S.P. headquarters.

KEEPING THE UNITED STATES PHARMACOPOEIA UP TO DATE

The revision committee is alert to any need for new standards or revision of existing standards during the 5-year period during which each U.S.P. is effective. Interim revisions take one of two forms. For changes of relatively limited application and interest, interim revision announcements, in the form of releases to the pharmaceutical press, are issued, especially if prompt effectiveness is a consideration. For more extensive changes and for the publication of new monographs on drugs, supplements are issued; and each supplement includes also the entire content of all interim revision announcements released since publication of the main volume or of the previous supplement. Supplements are distributed without additional charge to each purchaser of a copy of the current Pharmacopoeia.

APPLICATIONS OF U.S.P. STANDARDS

It often suffices, in explaining the U.S.P. revision program to laymen, to say simply that its object is to insure that the three letters "U.S.P." will continue to be a mark of distinction, something like the letters designating an academic degree.

Of the several roles filled by the Pharmacopoeia, that of providing regulatory agencies with enforceable standards of purity and strength often obscures the other essential functions.

It is important that the U.S.P. possess the character of a legal document. As an official compendium under the terms of the Federal Food, Drug and Cosmetic Act and the counterpart statutes of the States, all of its provisions must lend themselves to the unrestricted use of the regulatory agencies. This creates demands for clarity of context and freedom from ambiguity which frequently preclude conciseness.

The Pharmacopeia serves medicine in two ways. First, it gives the practicing physician his most effective voice in determining the quality of the drugs he prescribes. Second, it assists him by listing those drugs that constitute, in the words of the first Pharmacopeia, therapeutic agents "the utility of which is most fully established." To fulfill these functions, the Pharmacopeia must reflect with fidelity the best practices of medicine and pharmacy in providing standards of purity and potency for drugs of established merit and necessity. To this extent, the U.S.P. is a therapeutic guide the soundness of which is tempered only by that of the judgment of those who select the articles recognized. Yet, by its nature, the process of selection can scarcely be perfect, for no means has been found to insure, at least by the time of publication, that all drugs included are of equal merit and that no other equally meritorious are omitted. In view of today's rapid progress in medical sciences, a varying degree of lag is inevitable.

It is equally important to recognize some of the things that U.S.P. status does not affect. For example, numerous U.S.P. articles are subject to patent rights. The board of trustees long ago decided that the existence of such rights constituted no bar to U.S.P. recognition. In fact, the U.S.P. would be quite incomplete if patented drugs were left out. The U.S.P. listing does not modify patent coverage in any way, either here or abroad. The Pharmacopeia does give notice, however, on the back of the title page that the inclusion in the Pharmacopeia of standards for a patented or trademarked article does not convey any right or privilege protected by the patent or trademark.

WHAT "U.S.P." SIGNIFIES

The term "U.S.P." acquires its greatest significance from the prestige of the organization behind it. This is doubtless enhanced immensely by the knowledge that the U.S.P. standards are enforced by the Food and Drug Administration.

U.S.P. purity standards are minimums, or floors beneath which the level of purity may not fall. Thus, U.S.P. aspirin must be not less than 99.5 percent pure by actual assay.

Not infrequently, advertising claims are made to the effect that an article "is better than U.S.P." What is meant, of course, is that it assays above the U.S.P. minimum. Because of such claims, the general notices pertaining to all U.S.P. standards specifically state that the minimum purity tolerances specified for pharmacopeial articles other than dosage forms are established with a view to the use of the articles as drugs. Such limits do not bar the use of lots of an article which more nearly approach 100 percent purity nor do they constitute a basis for a claim that such lots exceed the pharmacopeial quality.

Some U.S.P. limits are maximums, as, for example, the limit on the time required for a tablet to disintegrate under specified test conditions. For instance, the maximum disintegration time permitted under the present U.S.P. standards for aspirin tablets is 15 minutes. The important point, nevertheless, is that aspirin tablets that disintegrate in as little as 2 to 3 seconds are still U.S.P. tablets.

THE LEGAL STATUS OF THE U.S.P.

Since 1906, the U.S.P. has been recognized by Federal statute as an "official compendium." As such, it provides the standards of strength, quality, and purity for the articles that it describes and defines. These standards constitute the basis for enforcement of the Food, Drug and Cosmetic Act in respect to drugs moving in interstate commerce. The U.S.P. serves the same purpose for enforcement of the counterpart legislation at the State level.

This role of the U.S.P. in providing a base for law enforcement is not generally regarded as a delegation of legislative power by the Congress. This view was most recently upheld in 1953 by the Supreme Court of the State of Wisconsin. The role, however, is obviously in keeping with the separation of legislative, executive, and judicial functions that it so firmly established in our form of

government. Because the U.S.P. is available, the Food and Drug Administration, for example, is not obliged to make regulations which later it must enforce.

It is essential to point out a very important limitation on the authority given the U.S.P. under this arrangement. This is that the U.S.P. standards apply only to articles intended for use as drugs. The use of a U.S.P. title or synonym brings an article squarely within the scope of the standards.

THE NATURE OF U.S.P. TITLES

Drugs selected for recognition in the U.S.P. are described under their respective nonproprietary or generic names. With rare exception, these names have been in use for months to years, so that the U.S.P. revision committee has the rather restricted option of taking, as the U.S.P. title, the name already in use or else changing it. The latter alternative is scarcely attractive in view of the confusion that is bound to result even if the name seems to be quite unsuitable for any one of a variety of reasons.

Actually, the United States lacks any very specific official procedure for assigning nonproprietary names to drugs.

THE U.S.P. HEADQUARTERS AND STAFF

The U.S.P. maintains permanent headquarters in the Pharmacopeia Building, at 46 Park Avenue, in the Grand Central area of New York City. The headquarters property was purchased in 1949, largely through generous response to a once-in-a-lifetime appeal for financial contributions, and is now maintained out of current income. The Pharmacopeia Building houses the small permanent staff that directs the U.S.P. program and provides space for the numerous conferences necessary to working out problems of drug standardization.

The U.S.P. staff consists of three persons who have scientific training in pharmacy or the allied sciences and a secretarial staff of three to four persons.

FINANCIAL SUPPORT OF THE PHARMACOPEIA

The funds required to finance the pharmacopeial program are derived mainly from the proceeds of sale of the Pharmacopeia. The price per copy has always been set to return only enough to meet conservative estimates of the expenses of the revision program.

It has been possible to keep the price low because a substantial part of the true cost of the program is contributed voluntarily by physicians and other scientists located over the entire country. The physicians include both private practitioners and physicians engaged mainly in teaching or research. The other specialists are engaged variously in teaching, retail or hospital pharmacy, or in one or more phases of producing drugs. Finally, a considerable amount of welcome help is received from Government scientists, both here in the United States and in Canada. Yet no tax money has ever been earmarked for U.S.P. revision.

It will be clear from these brief comments on the financial structure of the U.S.P. revision program that careful stewardship is obligatory. Nevertheless, the U.S.P. Convention is proud of what it accomplishes through the cooperative efforts of the professions of medicine and pharmacy and the Government in behalf of the public health and welfare.

Mr. MILLER. Some comment is needed in addition to that for present purposes because of the unique character of the U.S.P. Convention. As an institution, it dates back to 1820 and actually was organized in the Senate Chamber of our Capitol. Regularly, at 10-year intervals since then, the medical and pharmaceutical colleges and the State and National societies of these professions have been asked to send delegates to it. They and delegates from seven Federal agencies, including the Departments of Defense, and Health, Education, and Welfare, have but one duty, namely, to provide for revision of the United States Pharmacopeia during the ensuing decade. For this purpose, a revision committee of 60 members is elected and is charged with selecting those drugs that reflect the best teaching and practice of medicine and ultimately seeing that standards of potency and pur-

ity are developed and published for those drugs in what is better known among pharmacists and physicians the world over as simply the "U.S.P."

In 1906, and again in 1938, the Congress recognized the U.S.P. as an "official compendium" for the purpose of enforcement of Federal food and drug laws; and H.R. 11581 continues this recognition.

A board of trustees, also elected by the convention, is mainly concerned with maintaining the legal and financial standing of the pharmacopeia.

The 60-member committee of revision which I mentioned earlier is drawn from the entire breadth of medicine and pharmacy. The members, 20 from medicine and 40 from pharmacy and the allied sciences, serve as individual experts and not as "representatives" of their respective institutions. Advisory boards of experts outside the committee of revision may be appointed to consider special problems.

The convention undertakes to revise the U.S.P. completely every 5 years, and to issue interim supplements as needed; it is so highly respected that in doing so it can draw freely upon the knowledge of experts in medicine and pharmacy throughout the Nation, including experts employed by the Government. The convention is able thereby to overcome such handicaps as are imposed by limited financial resources. Indeed, the U.S.P. program is conducted on a very modest budget, inasmuch as its sole support is the net income from the sale of the book and of standard samples of drugs made available for reference purposes. No grants or subsidies are received from either State or Federal tax revenues.

From a vantage point of nearly 150 years' experience with drug standards, our board of trustees has studied the various legislative proposals for drug law revision now before the Congress, including H.R. 11581. The board is especially interested in those sections of the proposals that deal with extension of presale certification to all antibiotics and with choosing common names for drugs. The board wishes to record its opposition to additional certification, and puts forward an alternative to what H.R. 11581 would do in respect to drug nomenclature. The purpose of the remainder of my statement will be to make clear the reasons for our position.

OPPOSITION TO EXTENSION OF ANTIBIOTIC CERTIFICATION

Our opposition to the extension of certification of the antibiotics as proposed in H.R. 11581 rests in large measure on the fact that the concept of certification violates the basic principle upon which regulatory enforcement of drug standards has stood since the first Federal law in this field was enacted in 1906. The principle was reaffirmed in 1938, but in 1940 it was breached for insulin-containing drugs and again more extensively shortly thereafter as a wartime measure to expedite the volume production of penicillin.

The point involved here is essentially legal in character and I should feel most reluctant to touch upon it were it not for the fact that it is too important to be overlooked.

We are indebted to Mr. Walter G. Campbell, who headed the Food and Drug Administration from 1927 to 1944, for perhaps the clearest exposition of the underlying philosophy of this aspect of the food

and drug law. Mr. Campbell was trained as an attorney and devoted his entire career to public service in food and drug law enforcement. It was his view that to be able to depend upon standards for drugs provided independently was a source of great strength to the FDA since thereby the Administration avoided being placed in the position of having to police regulations it had itself created. He regarded this division of authority as simply a manifestation of the basic separation of powers so fundamental to our form of government. The development of standards of purity for drugs is a simple extension of the legislative process by which the Food, Drug, and Cosmetic Act was enacted. The enforcement of these standards is an executive function entrusted to FDA, an agency of the executive branch of the Government. The batch certification of insulin preparations and the antibiotics, under standards of strength and purity which the Administration promulgates and subsequently applies in conducting its tests, places upon this highly respected Government agency the responsibility for serving at once as legislator, tester, and judge. We hold that if certification is not needed for the host of drugs whose quality is maintained through the development and application of U.S.P. standards it should be equally unnecessary for the antibiotics.

It is a fact, of course, that several antibiotics are distributed without presale certification. Indeed, of the 12 basic antibiotics recognized in the present edition of the U.S.P., only 4 are subject to certification. A fifth, chlortetracycline, was once so recognized but is no longer; standards for it are provided by the National Formulary.

Antibiotic certification requires duplication of costly testing. Persons or firms introducing an antibiotic drug into interstate commerce do so under the general provisions of the Food, Drug, and Cosmetic Act. This means taking full responsibility for having complied with certain basic requirements which apply to all drugs regardless of how much or how little they affect the course of a life-threatening disease.

Antibiotic producers pay the Food and Drug Administration fees totaling nearly $1 million a year to reproduce tests they have already conducted to demonstrate the satisfactory character of the lots of antibiotics in question. These fees must of course show up in the final selling price of the antibiotic, regardless of how dubious is the value of the doublecheck that the certification program provides. It is the position of the U.S.P. Board of Trustees that there is no longer a need for treating antibotics as a class any differently from other classes of drugs.

While it may be shown that the cost of certification is spread rather widely so that perhaps it amounts to about one-twentieth of a cent per dose, this figure is misleading, because it is equivalent to averaging the costs of a mouse and a mink; that is, payment for certification of antibiotics is based on fees per batch, and a large batch means a great many doses, and for a large manufacturer the cost per dose is very little.

However, the same fee is charged for a small batch, and for a small manufacturer the amount per dose may be very substantial.

If the expenditure of $1 million annually is largely wasted, then surely the public interest would be better served if the money were otherwise used. Indeed, this was the tenor of a report [1] to the Con-

[1] See "Review of Enforcement and Certification Activities of the Food and Drug Administration, Department of Health, Education, and Welfare, September 1960."

gress by the Comptroller General of the United States, wherein it was held that the Federal funds and manpower required for antibiotic certification might better be put to other uses.

No need for extending or even continuing antibiotics certification has been demonstrated. In support of this position, we should like to direct the committee's attention to the contrast between the nature of penicillin that was being produced in 1943 when certification was first conceived and the quality of the penicillin that is being produced now. In 1943, pencillin was being turned out practically by hand in batches produced using 1-gallon bottles. Now it comes out in huge batches that are started in vats holding as much as 18,000 gallons of fermentation mixture. The standards for 1943 penicillin were actually so rudimentary that they should not be compared at all with those of today, which fill over 3½ pages of fine print in the U.S. Pharmacopeia.

A more telling comparison comes from putting a vial of the 1943 product alongside a vial of today's pencillin. I happen to have here an unopened vial of 1943 commercial pencillin. Having had a part in its production, it is a memento of those days. This penicillin was produced by the methods best known at that time. The contents of this vial are amorphous. That means that they are not crystalline. You can see that they are a deep orange in color, and if I were to open the vial you would notice a strong, almost pungent odor. When produced, the contents had a potency of barely 100 units per milligram; but the stability was so poor that doubtless all therapeutic activity has now vanished. Although intended for intravenous use, this product would not meet today's requirements for freedom from "pyrogens" (substances that produce febrile reactions in man and animals) and potentially toxic impurities. Quite possibly it would fail the present more rigid test for sterility. In contrast, 1962 pencillin is as colorless as fresh-fallen snow. I have several samples here, and all are odorless, and indefinitely stable. Their potency is about 1,660 units per milligram.

In 1943, pencillin was scarce and costly (the price of this vial was $20) so that only 100,000 units were put into each vial. Today, this is considered to be a small dose so that the 1962 vial contains 500,000 units. Yet the actual weight of this five-times-larger quantity of purer penicillin is substantially less than the 1943 vial contents and sells for less than a dollar.

The purpose of making this comparison is to point out that under the conditions prevailing in 1943, the certification program served admirably to expedite the production of a product desperately needed by our Armed Forces, impure though it was. However, for the past 15 years our American pharmaceutical industry has been turning out penicillin of almost unvarying purity. The duplicate testing conducted by FDA has contributed nothing that would not have been achieved just as well under the provisions of the Food, Drug, and Cosmetic Act that require all drugs to be tested to demonstrate compliance with their label claims.

Finally, in the opinion of the U.S.P. Board of Trustees, the continued use of antibiotics certification appears to imply a failure of the system of providing purity standards through the official compendia. The argument for special handling of all antibiotics, including those forms used to treat mild skin disorders, for example, on the

grounds that they are used to a greater degree in life-threatening illnesses simply does not stand up on scrutiny when drugs such as digitoxin, the heart stimulant, are among those not subject to presale, batch certification.

The U.S.P. Board of Trustees, therefore, respectfully urges that H.R. 11581 be revised to eliminate the reference to certification of antibiotics, as now defined in the Food, Drug, and Cosmetic Act. At least, it would be a progressive step to limit certification to new antibiotics of uncertain purity and stability and, furthermore, to provide a positive means of dispensing with certification when it can be shown that the output is of uniformly high purity and stability.

STANDARDIZATION OF DRUG NAMES

Section 111 of H.R. 11581 proposes to authorize the Secretary of the Department of Health, Education, and Welfare to establish, under specified circumstances and through promulgation of regulations, "a single standard name" for each drug. Section 112 deals with how these names are to be used. This concerns, of course, only the nonproprietary names, not the trademarked brand names for drugs. This class of names is variously called generic, common, or public names. The term "nonproprietary name" is gradually coming into more widespread use because it is more specific and because it is used internationally.

As one of its basic objectives, the U.S. Pharmacopeia has been providing standardized nomenclature for drugs since 1820, more than 85 years prior to the passage of the first Federal regulatory drug law. This long experience emboldens us now to suggest a close examination of the reasons for proposing in H.R. 11581 that Congress make the Secretary of the Department of Health, Education, and Welfare responsible, either wholly or partially, for the names of drugs. We ask whether the goal is greater safety in the use of drugs, or whether it is economic in nature. If the objective is purely a matter of safety, then the adequacy of the present law, the Food, Drug, and Cosmetic Act, should be looked at more closely: if the objective is economic, relief should be sought otherwise than by amending a law dealing mainly with public health.

Confusion over drug names can jeopardize public health. That the identity of drugs has been uncertain in the past because of a multiplicity of names has been demonstrated amply in medical writing, public outcry, and the hearings on S. 1552. However, those who thoroughly understand the problem agree that its nature is such that there is no simple solution. Only a radical change in our trademark laws can bring about marked improvement, and there has been no substantial suggestion that this is wanted. Almost any change of this kind would involve the whole structure of drug distribution.

While the situation does not lend itself to genuine simplification, some improvement is possible. One witness who testified on S. 1552, Dr. Louis Goodman, professor of pharmacology, University of Utah College of Medicine, a most distinguished teacher and scientist, spoke from firsthand experience with naming drugs, as follows—and I quote from the record of the hearings:

> This nomenclature problem is sticky. I once believed that drug companies, on occasion, deliberately and gleefully proposed generic names so polysyllabic and

so unpronounceable that even a simon-pure pharmacologist would gladly settle for a short euphonious trade name in his teaching of medical students and in his lectures to practicing physicians. Upon becoming a member of the AMA Council on Drugs, I learned that I was wrong.

By the very nature of a generic name, it must give some indication of the chemical class of the drug concerned, it must include the full name of the salt (if the drug is marketed as the salt), it must give some hint as to the chemical relation to any prototype agent already in the field, and it must avoid any therapeutic connotations. Furthermore, conflict and confusion with existing names often limit the choice of a generic name, and, in addition, there are certain international conventions which must be observed. By virtue of these severe but necessary restrictions, I doubt very much whether generic names are ever going to be as attractive as trade names. The days of such short, agreeable, official names as ether, morphine, atropine, and digitalis are gone.

Dr. Goodman's well-stated comments extend for several paragraphs more and include a highly complimentary reference to an article of mine that is entitled "Doctors, Drugs and Names" that appeared in the July 8, 1961, issue of the Journal of the American Medical Association, and which is reproduced on pages 483–490 of part 2 of the hearing record on S. 1552.

By way of adding emphasis to Dr. Goodman's appraisal of the problem, we may say that, fundamentally, physicians and pharmacists seek what is practically, if not absolutely, beyond attainment. It is utterly unrealistic to hope that drug names can be as familiar as those of common foods, for example. Seldom are we confronted with the scientific counterparts of the names of well-known fruits like the apple, pear, peach, and so forth. Nor does commerce in fruits require each grower to identify his produce so exclusively by a brand name that anyone risks mistaking an apple for an orange; moreover, if that happened, little harm would result.

With drugs, the situation is far more complicated. Chemists who synthesize and manufacture drugs use chemical terminology which must be complex to be precise, for the molecules of today's drugs are generally quite complex. But even chemists tend to abbreviate these long chemical names so that we hear such terms as DDT for dichlorodiphenyltrichloroethane, which, as an insecticide, is also a drug for use in ridding surroundings, clothing, and even one's person of disease-bearing insects.

This human tendency to abbreviate cannot be legislated out of existence, so we must be resigned to seeing more and more of jargon consisting of combinations like DDT or for that matter, FDA, AEC, and so forth. But there is great danger in using such terms for drugs because of the risk of confusion. DDT, as a drug, is quite safe if used prudently to dust clothing and the skin, but it can be toxic if misused.

Quite a different drug has come to be well known by the initials DFP, short for diisopropyl flurophosphate. It is extremely toxic and always must be used with utmost caution. If DFP were written for DDT on a doctor's prescription or on orders to a nurse and the error was not caught by the pharmacist, tragedy could result. These two drugs are listed in the U.S. Pharmacopeia under the titles Chlorophenothane and Isoflurophate, respectively, nonproprietary names which we feel differ enough from each other and from other titles to rule out confusion.

Fortunately, trivial designations consisting of letter or letter-and-number combinations are comparatively uncommon and only as rare exceptions do U.S.P. titles include letters or numbers.

Until quite recently, nonproprietary names were chosen haphazardly in the United States despite earnest efforts on the part of the American Medical Association that were aimed mainly toward encouraging early selection and toward avoiding therapeutic implications. There was no real stimulus to brevity or to showing interrelationships between similar drugs.

In 1961, the America Medical Association and the United States Pharmacopeia joined forces in this area and in the past year what are now called U.S. adopted names have been given to about 170 compounds. Less than one-third of these compounds will eventually be marketed as drugs, but the selection committee is much less concerned over this "waste" of names than with making certain that the names that do come into use are suitable. The names adopted for compounds that do not prove out as drugs will serve a useful purpose in identifying the compounds in reporting test results in the scientific literature.

The secretarial expense of this program is borne wholly by the AMA as a public service, although the U.S.P. shares other costs incurred. The program makes no call upon public funds. We feel that it is gaining steadily in general acceptance and that all that it now needs is formal recognition of the same sort that is accorded the U.S.P. standards of purity for drugs.

Toward that end, we propose the following change in H.R. 11581: Delete the reference to section 508 at line 12 on page 17 of H.R. 11581 and substitute a new section:

> For the purposes of this Act, each drug shall be known by one and only one nonproprietary or common name. If it is an article recognized in an official compendium as defined in section 201(j) or is an article that was once so recognized, the common name shall be the principal title for the drug used in that compendium, provided that if it is an article that has not been recognized in an official compendium or if it is a mixture of two or more drugs in established proportions, the common name shall be the name selected for it by the body charged with the revision of the United States Pharmacopeia: *Provided*, That if no such name has been selected, the Secretary shall inform the body charged with the revision of the United States Pharmacopeia of the need for a name, and if that body fails within a reasonable time to provide a name which, in the judgment of the Secretary, is suitable, then the Secretary may promulgate regulations establishing a single, common name for such drug (or for such identical drugs), and shall publish the name together with any related or additional information which, in the judgment of the Secretary, is desirable to facilitate the correct and effective use of such name?

We believe that our proposed alternative would achieve the following purposes:

(1) Provide unequivocally that each drug have but one standard nonproprietary name;

(2) Establish that the titles used in the official compendia shall be the required nonproprietary names;

(3) Make the United States Pharmacopeia responsible for providing names for drugs not recognized in the official compendia: and

(4) Give the Secretary of Health, Education, and Welfare standby authority to see that the U.S.P. fulfills its obligations in respect to names.

We offer this proposal in the belief that it will meet all current and future needs and that it will answer all valid criticism against nonproprietary names.

However, there are two criticisms that our program cannot possibly answer. One criticism is that confusion results from having numerous trademarked names for a single drug. Obviously, those who object to a multiplicity of trademarks for drugs are, in effect, criticizing our trademark laws. A second criticism is that the Food and Drug Administration has neglected this area. With respect to this complaint, it is our view that more might be done under existing authority.

It may suffice simply to point out that the very first subsection of section 502 of the Food, Drug, and Cosmetic Act defines as misbranded any drug having labeling that is "misleading in any particular." Further on, subsection (e) requires that the labeling of drugs not recognized in an official compendium bear "the usual or common name of the drug, if such there be." It would seem to be a matter of simple logic that ordinarily only one name for a drug can be regarded as "the common or usual name" and where two or more names appear to be competing for this distinction, the FDA may readily assert which name is to be used, to avoid having labels become misleading in this respect at least. Thus, the problem of multiple nonproprietary names really should not require amending the Food, Drug, and Cosmetic Act. This act, however, does fail to chart a course of action for the case in which a drug has no common or usual name. Our proposal covers this situation and we feel that FDA needs only to make known that it will require use of U.S. adopted names. It also confers standby authority upon the Secretary of Health, Education, and Welfare of the same sort he now has under section 501(b) of the Food, Drug, and Cosmetic Act, that permits him to correct inadequacies in the tests and standards for drugs that appear in the official compendia.

We trust that we may continue to conduct our name-selection program, in such a way that the standby authority would never be invoked. We will welcome such assistance as the Secretary may give us. As grounds for optimism on that score, we may point out that the Secretary has not yet been obliged to promulgate a regulation to supplant a U.S.P. assay which he has adjudged inadequate for regulatory purposes.

To recapitulate, we feel that it provides a reasonable basis for opposing the intent and effect of section 105 of H.R. 11581 with respect to extension of presale batch certification of antibiotics. Furthermore, we hope that we have paved the way for consideration of such changes in H.R. 11581 as will end the certification of all antibiotics that are produced in substantially pure form. Finally, we hope that our suggestions on drug nomenclature will be acceptable and will result in some changes in H.R. 11581 to bring about recognition of the existing and effective system for the selection of nonproprietary names for drugs.

I want to thank you very much for the privilege of appearing here.

The CHAIRMAN. Thank you very much, Doctor, for your interesting and helpful statement.

Any questions, Mr. Roberts?

Mr. ROBERTS. Doctor, with reference to the convention, I believe you stated you undertake to revise the United States Pharmacopoeia every 5 years, a complete revision.

Mr. MILLER. Yes.

Mr. ROBERTS. And you issue supplements as needed. How do you determine when you need an interim supplement?

Mr. MILLER. We have the tests and standards under study at all times. We receive complaints that this or that may be inadequate—suggestions more often than complaints—from several sources, the Food and Drug Administration being perhaps our most fruitful source, because the FDA is applying these tests itself every day in its laboratories.

We find the producers of drugs themselves are helpful and fruitful sources of suggestions. Our own committee members are conducting the tests that are specified in the Pharmacopoeia. And they occasionally find shortcomings. Or, as frequently happens, new methods are developed by scientists to apply to the existing drugs, and we endeavor to work them into the official tests just as soon as we can perfect them.

Mr. ROBERTS. How long have you been in your present position?

Mr. MILLER. Since 1950, 12½ years.

Mr. ROBERTS. You have had quite a bit of experience in this matter of designation of drugs. Now, are new drugs entering the field more rapidly now than they were when you first came to this work?

Mr. MILLER. Yes and no. Up until a year or so ago they were. There has been some slacking off within the last year and a half, but certainly the records show that the number of new drugs is increasing with the passage of time.

In 1960 there were nearly 50 new drugs, whereas in 1950 the number was between 30 and 35. I am speaking of new drug entities, not the dosage forms or combinations.

Mr. ROBERTS. You mentioned the fact that you received complaints sometimes. In what form or forms do these complaints take?

Mr. MILLER. Various forms.

Mr. ROBERTS. A description of the drug and its properties, or what?

Mr. MILLER. Yes. These pertain exclusively to the technical aspects. The melting point of the drug as we set it forth may be slightly different than that which is correct. Without getting too technical, the assay may be giving a slightly low result because of such a thing as increased solubility which we didn't recognize, so that we change the assay to correct that slight deficiency, and the result then is more nearly correct. That is the sort of thing, if I make my point clear.

Mr. ROBERTS. In your example of penicillin I take it that you mean by that that since its introduction during the war, I believe it was 1943, it has now reached the point where it is very stable, and as you pointed out the pyrogens and impurities are not prevalent as they were in the first experiences that we had with it.

Mr. MILLER. Yes, sir.

Mr. ROBERTS. Do you indicate by that line of reasoning that you think there should be a grandfather clause written into 11581 for these drugs that we have seen and used and experimented with over the period of years?

Mr. MILLER. Rather the reverse, I should think, if I interpret correctly your use of the grandfather clause. By grandfather clause I would understand you to mean we should blanket into a new regula-

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tion something that has been exempt theretofore. I would rather put it the other way around.

Mr. ROBERTS. Here is the thing that gave me that impression, and maybe we can straighten it out. You say, "At least it would be a progressive step"—after you were talking about the provision to eliminate the reference to the antibiotics—you don't have the number.

Mr. MILLER. Page 7.

Mr. ROBERTS (reading):

> At least, it would be a progressive step to limit certification to new antibiotics of uncertain purity and stability and, furthermore, to provide a positive means of dispensing with certification when it can be shown that the output is of uniformly high purity and stability.

Mr. MILLER. May I make that clear?

Mr. ROBERTS. Yes, sir.

Mr. MILLER. What I mean to say is that all five of the present antibiotics that are now required to be certified are being produced in a state of high purity and stability. Certification really isn't needed for them any longer. It once was, but isn't now.

New antibiotics are coming along, however, which are in a state of purity that these others were 15 to 20 years ago, and if certification is to be continued, it would make sense, it seems to me, to restrict it to these new antibiotics but only for such period as they are being produced in an impure and possibly less stable state.

And when the technology improves so that these new ones are being produced in pure state, then let's get away from certification as being unnecessary and a duplication of testing effort.

Mr. ROBERTS. Can you name some of the new antibiotics that you think have not reached the point of stability and purity that penicillin has?

Mr. MILLER. Yes; I can. I could do better if I had access to the list of the 30 that——

Mr. ROBERTS. Would you like to supply that for the record?

Mr. MILLER. I would hate to put the finger on two or three of the new ones that might be less deserving of mention than some of the less pure ones.

Mr. ROBERTS. Let me suggest that you supply that for the record.

Mr. MILLER. I would be glad to do that; yes.

Mr. ROBERTS. Now, this theory of one name or generic name for drugs, who first promulgated that idea, do you know?

Mr. MILLER. Of having a single name?

Mr. ROBERTS. Yes, sir.

Mr. MILLER. I couldn't say. I would suppose that it probably originated from frustrated teachers of pharmacology, as I was once myself, when they were obliged to use several names in order to make sure that students understood what was being taught. More recently—in trying to get at the origin of the suggestion—more recently, the idea has grown up with an economic aspect, that is, if the so-called generic or nonproprietary name were given more prominence, at the expense of trade names, the thought is that that would result in lowered costs of drugs.

I think it is a fallacy, but I don't believe that we need to go into that particular aspect. The idea, I think, is perfectly obvious and sound, to have only one name for a compound, in general, is a good thing.

Mr. ROBERTS. Don't you think it would be very difficult to do in view of the many complex chemical combinations that make up some of these compounds?

Mr. MILLER. No. I must not have made my point. I think it is quite feasible to have one nonproprietary name for each compound. We must also have a chemical name which will be long and complex and precise. And that is all right. That will be in the chemical literature. And it will identify this nonproprietary name when properly used. But for the physician and for the pharmacist, we can very well have one single nonproprietary name for each drug.

Mr. ROBERTS. And you believe the Food and Drug Administration has that authority under the present law?

Mr. MILLER. I think they do. I think that they could long ago have said, when a new drug application came in, that used a strange and new and contrived name, they might very well have said, "Well, this drug has been in numerous combinations for which new drug applications have become effective, and in those it was called, let's say, ABC. But here you propose to call it XYZ. We believe that to avoid confusion and protect the public health that you should call it in your labeling just like everyone has done earlier." But FDA have not done that; in fact, they seem to have gone out of their way to have avoided doing it.

Mr. ROBERTS. You were with Food and Drug for 9 or 10 years, I believe?

Mr. MILLER. That is right. I wasn't in the new-drug branch. I was in the Pharmacology Division.

Mr. ROBERTS. And you had a good relationship, I mean your committee with the Food and Drug?

Mr. MILLER. The closest and most cordial; yes.

Mr. ROBERTS. That is all I have, Mr. Chairman.

The CHAIRMAN. Mr. Glenn.

Mr. GLENN. Doctor, after the USP sets these standards do you or any allied organization take it upon yourselves to see whether the industry is complying with using these standards?

Mr. MILLER. Not in the police sense. We do from a technical standpoint, to see if the standards are feasible and practical, but it is the responsibility of the Food and Drug Administration to police them as a part of the executive branch of the Government. If we were a part of the Government, we would belong to the legislative branch. In fact, it is not infrequently said that our function is an extension of the legislative effort of the Congress. Indeed, it was alleged in court one time that Congress must have exceeded its authority in having delegated to the USP this function back in 1906. But the Supreme Court of the State of Wisconsin ruled otherwise.

Mr. GLENN. You have said that you do exercise name selecting.

Mr. MILLER. Yes.

Mr. GLENN. And if this bill is enacted into law, is it your contention that the Secretary will then take over the jurisdiction which you are now exercising?

Mr. MILLER. He certainly will be authorized to do so. Because the words are "may promulgate regulations." I think it is not obligatory, but he is given the right to do so. And furthermore, the terms of the bill before the Senate are such now—I haven't had a legal expert inter-

pret them for us, but the terms are such that he is required to do certain things. He is required to review the titles of the U.S.P., and he may change them if he feels that they could be simplified and made more useful.

And I think boiling it down, a page and a half of this bill to two sentences, that seems to be the intent of the present form of H.R. 11581.

Mr. GLENN. Thank you very much. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Curtin.

Mr. CURTIN. I take it from your statement, Doctor, that you would rather see all drugs designated by the full technical name rather than initials; is that correct?

Mr. MILLER. If you will permit me to use the term "nonproprietary name" instead of "full technical name," yes. But if you mean the chemical name, the complex chemical name, no. We think the use of initials is abominable and dangerous. But this is a terribly complex subject. For complex molecule that has a long and difficult-to-pronounce name, that is, the full chemical name, we try to give a name of three, four, six syllables which will be the nonproprietary name that will be assigned to that compound and that alone.

Mr. CURTIN. The so-called generic name?

Mr. MILLER. The so-called generic name: yes.

Mr. CURTIN. When a doctor is writing a prescription to be filled by a druggist, doesn't he normally use these initials rather than the full generic name?

Mr. MILLER. Too frequently the pharmacist has to exercise his powers of guessing what the doctor meant. If he is uncertain in any respect he will check back with the physician, and you can guess at what that gives rise to, because the physician thinks that the pharmacist ought to know, be smart enough to guess what he meant, and so on.

But the physician should be more specific, if I were to be allowed to criticize him.

Mr. CURTIN. You call attention in your statement to the distinction, for example, between DDT and DFP.

Mr. MILLER. Yes.

Mr. CURTIN. Human nature being what it is, don't you think that doctors are still going to use those initials when they write prescriptions, regardless of what you people recommend or what the law may say?

Mr. MILLER. If he persists in disregarding what he is taught, he may. But doctors are generally pretty careful to be specific. But there are areas in which they abbreviate, particularly in prescribing the biologicals, which have terribly long names.

Mr. CURTIN. And that is going to continue?

Mr. MILLER. That is going to continue.

Mr. CURTIN. This practice is going to continue in doctors' prescriptions, regardless of what we say or do here; isn't that true?

Mr. MILLER. Yes. The U.S.P. was once asked to set up a standard set of abbreviations, as is done in England. The British Pharmacopeia has a standard set of abbreviations where such would be appropriate. And this was one of the suggestions that we received one time.

We went to the Council on Drugs of the American Medical Association, and you could hardly imagine anything being denounced more roundly than that suggestion was. We went to the NIH—the National Institutes of Health—which licenses producers of the biologicals. They were unalterably opposed to the idea that the U.S.P. should set up standard abbreviations for the biologicals.

Mr. CURTIN. What do you think about it? Don't you think it is a practical suggestion?

Mr. MILLER. If I had not, I wouldn't have taken time to consider it. I felt as you have indicated a moment ago, doctors are human, and tend to be a trifle lazy in writing prescriptions. So I felt that it might help to have standard abbreviations.

Mr. CURTIN. It would seem to me that the greatest need for being very clear in what drug is being described is in the field of writing a prescription rather than in an article on the drug or public mention of it in an advertisement, because there the danger from a mistake is much less than it is when a doctor is saying to a druggist, "This is what I want the patient to have."

Mr. MILLER. And he is more likely to be short of time when he is writing prescriptions than when he is writing an article for a medical journal.

Mr. CURTIN. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Moss.

Mr. Moss. Dr. Miller, you have apparently two major objections to the legislation now before us. The first, the batch-by-batch certification?

Mr. MILLER. Yes.

Mr. Moss. And then the matter of name designations?

Mr. MILLER. Yes. I wouldn't go so far as to put the two in the same degree of opposition.

Mr. Moss. No, I understand one you are flatly opposed to certification.

Mr. MILLER. Yes.

Mr. Moss. And the other you suggest a modification to which would ultimately reach the same result.

Mr. MILLER. I think so, yes.

Mr. Moss. I can thoroughly understand the latter objection. The first one is more difficult. You have no function in your role with the U.S. Pharmacopeia of checking any of these products once there has been an agreed upon standardization?

Mr. MILLER. Our function is that of providing purity tests and standards.

Mr. Moss. Are you familiar with Dr. John L. Harvey?

Mr. MILLER. Yes.

Mr. Moss. In a speech given by him on August 8 in San Francisco, to the American Bar Association, discussing this question of certification, he stated that—

> Batch-by-batch certification of all antibiotic drugs is needed because: (a) more than any other drugs, antibiotics are the first choice in treating life-threatening infectious conditions.

I think it has been frequently charged that they are too readily resorted to in many instances without proper evaluation of the effect which might arise when they would be more critically needed.

(b) Most antibiotics are produced by complex processes in which both the desirable antibiotics and quantities of undesirable byproducts are manufactured.
(c) The potency of antibiotics must be determined by biological assay procedures, the interpretation of which requires unusual competence.

Do you disagree with any of those statements?

Mr. MILLER. I would not disagree with them, but I would hold that the antibiotics are not at all unique in that respect.

Mr. Moss. They said "despite the manufacturer's check." Well, unique in one respect in that more than any other drugs—if you agree with his statement——

Mr. MILLER. No; I do not think so.

Mr. Moss. You do not think they are resorted to more frequently than any other?

So if you accept that statement as being accurate——

Mr. MILLER. On a quantity basis, of course, because about one-third of the drugs used in terms of volume are antibiotics, so that you cannot deny that.

Mr. Moss. He said:

Despite the manufacturer's check of each batch of antibiotics before submitting it for certification, in fiscal year 1961 samples from over 100 batches offered for certification—

we are dealing now with only the five?

Mr. MILLER. Yes.

Mr. Moss. Not the other 25?

Mr. MILLER. No.

Mr. Moss (continuing):

failed to meet the standards set forth in the regulations.

Mr. MILLER. What was the percentage?

Mr. Moss. It does not relate it to percentage.

Mr. MILLER. I see.

Mr. Moss. He said samples from over 100 batches offered for certification failed to meet the standards set forth in the regulations.

Mr. MILLER. Mr. Harvey has the records. I would not challenge that figure at all, but I would offer this, knowing some of the circumstances.

Whether this pertains to the year that he is speaking of, but this used to be the practice among the antibiotic producers:

That when a batch has been finished and their tests had reached a stage that they felt reasonably sure that the material was satisfactory, they dispatched the FDA sample to Washington, so that Washington might start its testing in order that they both might get done sooner.

In many cases, and it used to be prior to—not long ago—I should not say "many"; occasionally, let us say—the producers would find in completing their tests that in some respects that the batch did not live up to the requirements.

It used to be that they could withdraw that sample and say, "We wish to withdraw the application for certification."

For some time now, Food and Drug has refused to permit them to withdraw, but has been counting that sample as a rejection.

As a result, I understand within the industry that they are now completing all of their tests, such as they would do, in any case, before they put the drug on the market, before sending a sample to the Administration.

Mr. Moss. This would be very current practice?

Mr. MILLER. Yes.

Mr. Moss. Because it is for the 1961 fiscal year?

Mr. MILLER. Yes.

With respect to how much there has been, it would be very relevant to inquirie in just what respect these 100 samples failed. I would be greatly surprised if these were very significant deficiencies.

Mr. Moss. Of course, the question is as to the currency of your own experience as contrasted to the material developed within the Food and Drug Administration.

Mr. MILLER. I am quoting this experience——

Mr. Moss. If we accept the fact that Dr. Harvey is a reliable and informed source of information, he cites this as an illustration of the need for not only a continuing of the existing practice, but an extension of it.

Mr. MILLER. Yes.

Mr. Moss. I would assume that he is competent to make such a determination.

Mr. MILLER. He certainly has access to the record.

What he has not said and indicated, in citing 100 instances, whether those were material deficiencies, whether they were very serious or they simply had a misspelling on a label or something of that kind.

Mr. Moss. Do you think, if they were not material instances, that from them he would conclude that a need existed for a continuation of this practice?

What motivation might be anticipated?

Mr. MILLER. Mr. Congressman, the Food and Drug Administration carries out a very substantial part of its testing program on the basis of fees collected from manufacturers, fees which are determined by them as being essential.

Therefore, it somewhat relieves the Food and Drug Administration of coming to Congress for appropriations.

Mr. Moss. Well, now, let us examine that carefully.

Do you know this as a fact: That it relieves them from coming to the Congress for the appropriation? There are many agencies, such as the Post Office Department, that collect a lot of fees.

Mr. MILLER. Yes.

Mr. Moss. But, Doctor, believe me, they come to us for the authorization for every dollar they expend.

Mr. MILLER. I realize that.

Mr. Moss. And I doubt very much that this money collected in fees goes into some fund exempt from reappropriation by the Congress.

Mr. MILLER. May I ask that you check into that before the latter part of this week.

Mr. Moss. I will check, certainly, but I would hate to think that we are dealing with an agency so unreliable that fees approximating $1 million a year, and that, related to its total budget, is rather an insignificant portion of it—that this bait influences their judgment to give misleading advice and unfounded advice to this Congress.

If that were true, Doctor, then I think we should make a most searching inquiry of this operation, because it would not be at all responsible.

I do not like to see that sort of motivation attributed unless you have some basis for so intimating.

Mr. MILLER. I would be the last one in the world, because I have so many good friends in Food and Drug Administration, to attribute any motives but the best to them, but it is my understanding and it is the understanding of the industry——

Mr. MOSS. You just indicated a rather base motivation.

Mr. MILLER. I am indicating that Mr. Harvey wants to make a good case for maintaining certification.

Mr. MOSS. In order to get the the fees?

Mr. MILLER. In order to get the fees.

Mr. MOSS. Mr. Chairman, I might observe that is a most amazing statement, and does no service to Dr. Harvey.

Mr. MILLER. If it is a disservice, I want to apologize publicly to him and to the committee.

Mr. MOSS. On that basis, then, sir, I note that the Pharmacopoeia is supported by two sources of revenue. I was not going to mention it, but if we must be so suspect of those who appear before us as to their motives, what are yours in this, and what do you derive from the sale of sample drugs?

Mr. MILLER. These are reference standards that are required for the carrying out of the assays.

Mr. MOSS. Yes.

Mr. MILLER. And it might be said that we write into our assays the need for standards that one would have to have, but I can assure you that it is so much trouble for us to put these out that that is certainly not the reason they go into these tests.

Mr. MOSS. You state here that inasmuch as its sole support is the net income from the sale of the USP and from standard samples of drugs made available for reference purposes, that I assume that the revenue derived from this activity contributes to the support of your shop?

Mr. MILLER. Yes.

Mr. MOSS. And does this influence, in any way, any of the judgments you make here or the advice you give this committee?

Mr. MILLER. I assure you that it does not.

Mr. MOSS. But you think that the personnel of Food and Drug is just a little less pure in motive than you?

Mr. MILLER. No, I would not, Mr. Congressman, wish to impugn——

Mr. MOSS. I am concerned because you are a former employee.

Mr. MILLER. Yes.

Mr. MOSS. And you are talking about former associates, and it is an amazing statement and a disturbing one to me to hear you make it.

Mr. MILLER. And, if I am not wrong, it should be disturbing.

I have the recollection one time of Mr. Larrick having been explaining this system before the Appropriations Committee of either the Senate or the House—I suppose it would be the House—where it was suggested that all drug testing be put on a fee basis, and Mr. Larrick indicated that that would put him in a very embarrassing position.

Mr. Moss. Doctor, I think this matter of whether an industry being policed should pay the cost of the administering of the program is one that is not related solely to Food and Drug.

This committee, as you know, has rather a broad jurisdiction, having all of the regulatory agencies of the Government, the independent regulatory commissions.

Mr. MILLER. Yes.

Mr. Moss. You are probably aware that it costs a lot of money to regulate television and radio.

Mr. MILLER. I am sure it must.

Mr. Moss. There are many who feel that we should impose fees to recover all of this cost and perhaps it would be good business, but I think that whether or not you show a fine record on fees when you only produce a piddling $1 million a year in a budget of the size of the one Food and Drug has is really unworthy——

Mr. MILLER. At one time their budget, when this $1 million was substantially what it is now, their budget was in the neighborhood of $12 to $14 million.

Mr. Moss. It is not too many years ago that the budget of the United States was less than the cost of the interest on the debt at the present time, sir.

They all grow.

You would not want me to conclude in this vein of suspicion of motives that the objective in the proposed amendment to the section 508 or substitution of 508 is in order to continue your very excellent and well-reputed publication in business, would you?

Mr. MILLER. You certainly might assume that.

Mr. Moss. I do not.

I think you feel you render a service and that you are competent to render it and there would be no need to duplicate.

Mr. MILLER. I do no like to attribute that sort of motivation to people.

Mr. Moss. I hope you will not sincerely.

Mr. MILLER. I would not want to.

Mr. Moss. I might add that in your statement you appear to have an error here.

I think you are not wanting to delete but rather to substitute language on page 17.

Mr. MILLER. That perhaps is a better word.

Mr. Moss. What you are seeking here in this proposed amendment, then, is to have the Secretary first exhaust the resources of existing, recognized sources before, on his own, designating a name for any drug. But you feel that there is sufficient justification for arriving at simplification of terminology that it should be achieved ultimately?

Mr. MILLER. We think, yes, that he should use the existing system which costs the Government nothing; a voluntary and, I hope we can say, democratic process for arriving at names which is working, and we think working real well, should be used, instead of burdening the Food and Drug Administration with this business of selecting names.

Mr. Moss. Of course, I had assumed that this would probably be the sort of rule or regulation the Secretary would adopt under the language as it is in the bill, in order to achieve the final objective of the simplification of name or terminology.

That is all the questions I have, Mr. Chairman.

The CHAIRMAN. Thank you very much.

Mr. MILLER. Thank you, again.

The CHAIRMAN. I might advise the committee that we have four other witnesses this afternoon.

Mr. Fred L. Van Aalst?

We are very glad to have you with us, and we will be glad to have your statement.

STATEMENT OF FRED L. VAN AALST, CONTROLLER, FLEUROMA, INC.

Mr. VAN AALST. Mr. Chairman, my name is Fred L. Van Aalst. I am the controller of Fleuroma, Inc., New York. We are members of the Essential Oil Association of the U.S.A., and fully support the statement which will be made before this committee by its president, Mr. Frank F. Dittrich.

I appear on behalf of my company, in opposition to section 201 of H.R. 11581, the factory inspection authority, which is the only provision in this bill that concerns my company directly.

Fleuroma, Inc., is in the business of creating, manufacturing, and selling perfume bases, and we have limited ourselves to this highly specialized field. We do not make or sell any finished cosmetics or other consumer product; nothing we make is sold, as such, to the public. Our perfume bases are sold to the manufacturers of finished cosmetics; they are our customers.

My company was started in 1946 by two partners who invested not only all of their savings and money borrowed from friends, but also unique craftsmanship, excellence, and experience into this venture. When we started in 1946, in a small garage-type building, we had a staff of three. When I joined the company, we had 12 people. Today we are still small, employing about 80 people; but our sales are now in the millions of dollars, and we have carved a niche for ourselves in this industry. We are highly regarded for our creative ability, and count most of the largest and best known cosmetic companies among our customers.

Permit me to emphasize that our work requires creative ability, unique talents, and true artistic qualities—rather than the application of a skill or trade. By selecting and blending scores and often hundreds of ingredients from among the thousands available, each one of which we must know intimately, and after carrying out countless experiments which often stretch over periods of years, we finally produce the fragrance that will be the heart of a new perfume, cologne, or cosmetic preparation. This blend, when finally established as a result of this long and painstaking procedure, is recorded as a formula which goes into our files.

Obviously, this formula represents all of the talent, all of the artistic creativity, and all of the accumulated experience of which we are possessed.

Like every responsible citizen, I want to see the welfare and safety of the public protected. I have spent most of my working life in the business of perfume bases, and naturally am in close contact with the manufacturers of finished perfumes and cosmetics. My company alone, during its existence, has sold perfume bases that must have

been used in the production of billions of bottles and jars and tubes of perfume, cologne, creams, and powders. I know of no cases of injury or harm of any kind as the result of the use of perfume bases.

The factory inspection provision of H.R. 11581, if applied—as this bill now proposes—to the creators and manufacturers of perfume bases, would add nothing to the safety of the public. However, the inevitable losses which would result from the inspection and the consequent violation of the secrecy of our formulas would be a tragic blow to my company and other companies in our field.

If we believe that a man is entitled to the fruits of his labor; if we believe that he is entitled to safeguard his most precious possession; and if we believe that the laws should protect these rights, then the manufacturers of perfume bases should be exempt from the factory inspection provisions of H.R. 11581. For the sake of what is just and right, I appeal to you to do just that.

Thank you for the opportunity to make this statement.

The CHAIRMAN. Thank you, Mr. Van Aalst, for your statement, and certainly your plea will be given most careful consideration.

We are glad to have your statement.

Mr. VAN AALST. Thank you.

The CHAIRMAN. Dr. Bernard L. Oser?

STATEMENT OF BERNARD L. OSER, PH. D., PRESIDENT AND DIRECTOR, FOOD & DRUG RESEARCH LABORATORIES, AND CHAIRMAN OF THE FOOD AND DRUG ADMINISTRATION LIAISON COMMITTEE OF THE AMERICAN COUNCIL OF INDEPENDENT LABORATORIES, INC.

Mr. OSER. Mr. Chairman and members of the committee, my name is Bernard L. Oser. I am president and director of the Food & Drug Research Laboratories, Inc., Maspeth, N.Y., an independent consulting, research, and testing organization. I have the honor to address your committee in my capacity as chairman of the Food and Drug Administration Liaison Committee of the American Council of Independent Laboratories, Inc., an association of which our laboratories are a charter member and of which I was formerly president. The council was founded in 1937 and consists of 74 member laboratories with 171 headquarters and branch laboratories throughout the Nation.

Of special interest to our members is the proposal to include consulting laboratories in the factory inspection provisions of H.R. 11581. It is widely held in our profession, and by many in the industries we serve, that such unrestricted inspection as is contemplated would seriously compromise the confidential relationship existing between us and our clients. It would furthermore place laboratory administrators in a difficult and embarrassing position with respect to their obligation to guard the property and rights of their clients.

Independent consulting laboratories are not engaged in the manufacture or sale of foods, drugs, cosmetics, or devices; they are not factories in any commonly accepted sense of the term; their stock-in-trade is information or advice, and such laboratory services as they may render incidental thereto include basic and applied research and product and process development as well as analyses and assays.

These analytical services may be related to identity, purity, quality, or potency and may provide information for labeling purposes, but such services are only a part, and in many cases a minor part, of a consulting laboratory's activities.

It is pertinent to this discussion to contrast the Food and Drug Administration definition of a consulting laboratory with that of the American Council of Independent Laboratories for an independent laboratory which is a—

proprietorship, partnership, or corporation which is not affiliated in any manner with either a governmental agency or a tax-favored academic or research institution; or with an outside proprietorship, partnership, corporation, or trade association in any manner which may jeopardize its capacity to conduct investigations, render reports, or give professional council objectively and without bias.

In the FDA definition a consulting laboratory is—

a laboratory which for a fee or other remuneration, performs assays or other laboratory services for a manufacturer, processor, or compounder who owns or has under his control an establishment which (other than as a consulting laboratory) is subject to inspection under this section.

Bearing in mind that many universities, medical schools, hospitals, et cetera, regularly or occasionally perform such services under grants from industrial sponsors, it is apparent that the proposed regulation can readily be construed to encompass inspection of these institutions as well as of commercially operated laboratories. We cite this not to suggest that they should be excluded if they render such services, but to indicate the extremely broad scope of the proposed extension of authority.

To the best of our knowledge, no member of the American Council of Independent Laboratories, nor any other consulting laboratory, has ever denied a request on the part of a representative of the Food and Drug Administration to inspect its facilities. We have, in fact, urged such visitations and have welcomed the opportunity to display our physical facilities and equipment. It is regrettable that such invitations are not more frequently accepted since this would help acquaint responsible officials with the availability of our services to both Government and industry, for implementing the technical requirements of the Food, Drug, and Cosmetic Act.

In testimony before the Kefauver committee former Secretary of Health, Education, and Welfare Ribicoff stated that in the 32 months ending August 1961, 122 firms had refused to permit 1 or more phases of inspection "needed to make a complete determination of the legality of some phase of the drug business." I might add that he also said: "Most of the firms we inspect voluntarily permit such inspections today."

No elaboration of the nature or source of these refusals was given to permit a conclusion as to whether or not any consulting laboratories were involved. However, Commissioner Larrick has acknowledged that "the desirability of mentioning independent laboratories in connection with any new legislation is not, so far, occasioned by refusals of such laboratories to permit inspection." An extremely rare situation has been cited where a laboratory, suspected of rendering dishonest reports, was subsequently inspected by FDA and found to be unequipped to perform the pharmaceutical testing services it purported to render. In this instance a conviction was obtained by the

Food and Drug Administration under the present law. We seriously question the generalization implied in testimony before this committee that false reports given to clients by "some" laboratories make it necessary to broaden the existing inspection powers of FDA.

Thus, insofar as the inspection of facilities of consulting laboratories is concerned, the need for amended legislation does not appear to have been established, nor is it believed to exist. In saying this, however, a distinction must be made between inspection of physical plant and equipment, on the one hand, and records and files, on the other.

To the extent that the contemplated inspection is unrestricted and includes the examination of correspondence files, laboratory notebooks, and similar records and reports, or any inquiry into the scientific or technical qualifications of laboratory personnel, the American Council of Independent Laboratories wishes to register its unalterable opposition to this proposal. Our objection is predicated not merely on the possibility of fishing expeditions, to which reference has been made by other witnesses, but is based on the facts that much of the work of a consulting laboratory—and, hence, its files, records, and so forth—has no direct relationship to pending or proposed administrative matters; that services rendered for a specific client may relate to research projects or to the development and improvement of products which may not come within the scope of the Food, Drug, and Cosmetic Act; that such services, and hence records, may relate to products or processes not yet subject to patent protection, or may involve independently obtained data concerning competitive products, or they may relate to pending or proposed litigation to which a competitor or the Government itself may be a party. These are but examples of the highly confidential nature of the relationship between consultants and clients, a relationship no different from that which exists between lawyers and their clients, or between physicians and their patients.

A consulting laboratory having custody of secret formulas or other confidential information belonging to a client is not in the same position as the client with property rights in such information. The consultant should not be expected to assume the responsibility of deciding what and how much of his client's information may properly and legally be released; this should be the prerogative of the client, rather than of the service laboratory. The responsibility for withholding what he may legally be entitled to withhold should rest on the client's shoulders. Under the proposed amendment a manufacturer would be exposed to compulsory disclosure of confidential matters under circumstances beyond his control and a consulting laboratory entrusted with such confidential data might be criminally liable for guarding too zealously its client's interests.

The ultimate objective of scientific investigations which a consulting laboratory is asked to undertake is sometimes not disclosed even to the investigator. Under these circumstances it is difficult to decide what is pertinent to a food and drug matter and what is not, or what is control testing as distinguished from research. The line of demarcation between research and control testing is not so sharply drawn as to distinguish one type of record from the other. This is not to deny that where a clear distinction does exist, and a request is made for specific analytical control data, they should be made avail-

able for inspection. But for this purpose it seems unnecessary to expend present inspection powers to the degree that irrelevant confidential information might also be disclosed.

It has been contended that any information made available to a food and drug inspector is treated confidentially and that trade secrets have never been known to be revealed except when necessary in administrative or judicial proceedings. In such statements, the qualification must be recognized that no such instances are "known." This does not mean they do not exist or may not occur. Without questioning the claim of the Food and Drug Administration for a good record in this respect, it must be acknowledged that proof of a breach of confidence or misuse of private information is extremely difficult to establish. To say that no known violations have occurred is tantamount to claiming a drug to be safe simply because no adverse effects are known. Scientific or technological information once impressed on a prepared mind cannot readily be erased. The application of such information, either directly or perhaps subconsciously under appropriate circumstances, is hardly avoidable. Furthermore, it is well known that Government agencies, like industrial organizations, are experiencing a constant turnover of personnel. What opportunity has the FDA or any other agency to check on the misuse of confidentially gotten information, once an individual has left its employ?

It has been claimed that adequate administration of the food additive regulations is hampered by the inability of FDA inspectors to look into production and control records in plants. It is certainly not news to this committee that practicable analytical methods are required for detecting the presence and amounts of additives to food, as well as for controlling the purity and potency of drugs. These methods are more definitive and unequivocal than self-serving production records. To the extent that inspectors might rely upon production or control records in lieu of independent analyses, it would tend to encourage the maintenance of duplicate or ex post facto records.

It has been proposed that FDA inspection be extended to include inquiry into the qualifications of technical personnel. The problem of certifying laboratories has been considered for many years and progress in this direction, particularly as applied to clinical laboratories, has been made in many States. However, the setting of standards of competence for scientific or technical personnel at different professional levels is fraught with many difficulties and has been the subject of concern among professional societies representing various scientific disciplines.

Under these circumstances it would seem logical that a prerequisite to any attempt to inquire into the qualifications of laboratory personnel should be the adoption of criteria, not unilaterally by FDA, but in collaboration with the appropriate technical and professional organizations. The complexity of this problem would seem to militate against the advisability of granting authority to inspectors to pass upon the qualifications of technical personnel. This should be the responsibility of the operating management of any organization engaged in scientific activities.

In summary, we respectfully submit that the inclusion of consulting laboratories with manufacturing establishments subject to the broad

inspection powers contemplated under the proposed amendment, is neither necessary nor desirable because (i) adequate authority for such laboratory inspection as is appropriate to the purpose of the act already exists: (ii) no evidence has been established that inspection under present law has been refused by a consulting laboratory; (iii) reasonable limitations have not been defined which would restrict inspection to specified analytical control data; (iv) no standards or criteria for the qualifications of personnel have been established by the pertinent scientific or technical professions; (v) no protection is afforded the consulting laboratory against disclosure of irrelevant or confidential information belonging to a client; and (vi) unrestricted inspection would impair the confidential relationship between scientific consultants and their clients to the extent of seriously jeopardizing their professional activities.

The CHAIRMAN. Doctor, thank you very much for your discussion of this particular problem, which I think is the first one we have had on the question of consulting laboratories.

Any questions by members of the committee?

Thank you very much.

Mr. OSER. Thank you.

Mr. MOSS. Mr. Chairman, I have no questions, but I wanted to have the record reflect the fact that the fees received by the Food and Drug Administration are, as I suspected, paid into the Treasury and subject to the annual appropriation by the appropriate committees of the Congress.

I think that the doubt raised by Dr. Miller's statement as to whether or not that was the procedure should be clearly resolved, and I had the matter checked with the agency in order to ascertain the truth.

The CHAIRMAN. Very well.

We think the record should speak what the facts are.

Dr. Miles H. Robinson?

Dr. Robinson, you may proceed.

STATEMENT OF MILES H. ROBINSON, M.D.

DR. ROBINSON. Mr. Chairman and members of the committee, I am Miles H. Robinson, a graduate of the University of Pennsylvania Medical School in Philadelphia, and for the last 20 years I have been in the practice of internal medicine in Washington State and in Maryland, with the exception of 4 years teaching and doing research in physiology and pharmacology at Vanderbilt Medical School in Nashville, Tenn., and at the University of Pennsylvania Medical School.

I am an independent, practicing physician, not connected in any way with the drug industry, and I have some facts with documentation to give the committee, which I believe are good reasons, among others, for passing H.R. 11581.

The fact that large numbers of children have been born without arms in Europe as a result of taking a tranquilizer drug also approved in this country for testing by the Food and Drug Administration seems reason enough to pass legislation to strengthen the safety provisions of the FDA.

Yet, there is a deeper significance to this tragedy which should be laid before this committee. It is that the people of this Nation are

being steadily educated by doctors and the drug industry to take a drug whenever they feel anxious about anything. They are thus diverted and distracted from really constructive actions to preserve health, and the moral fiber of the country is seriously weakened.

As Dr. Herbert Ratner, director of public health for Oak Park, Ill., says:

> * * * we must not forget that, with the barbiturates and stimulants, the tranquilizers are the most misused drugs in the United States. We consume fantastic quantities of these drugs. For many they are used as a panacea to solve personal problems; they are practically replacing the *function of the virtues* in striving for a sane and well ordered life.

The emphasis is mine. This quotation is from an interview printed in pamphlet form by the Fund for the Republic, Inc., Santa Barbara, Calif., 1962, page 34.

Dr. Ratner is making the point that the more tranquilizers, the less people are resorting, let us say, to the Bible and the Ten Commandments.

What is our consumption of tranquilizers? I have not heard that given in testimony before the committee. I was able to get yesterday the dollar volume for 1958 and the tonnage for 1961. In 1958, $200 million was spent on them; one-fifth of all Americans had taken them; 1 out of 3 prescriptions were for tranquilizers; and 20 million Americans were taking them regularly.

This is from a clipping from the Baltimore Sun in 1958, reporting a speech by the assistant professor of pharmacology at the University of Maryland Medical School.

In 1961, I have not got similar figures, but 7,200 tons were produced, which was 119 tons more than in 1960. This is just in the United States, and that reference is from Drug Trade News, August 6, 1962, page 55.

The thalidomide catastrophe is just the part of this iceberg, so to speak, which shows above the surface. Underneath the surface lie the potential consequences of continued intemperate ingestion of drugs, tranquilizers, and others. We have now had a strong warning and it may be a fortunate thing that we did not have to wait 20 years as in the case of cancer from painting radium on watch dials before we got this warning.

Who is promoting the widespread consumption of tranquilizers, and how do they do it? I would like to read very brief excerpts from typical misleading advertisements which the drug industry displays to doctors and which urge a fantastic use for drugs. I picked almost all of these advertisements out of my mail which came in the last few days.

This is a full-page advertisement on the back cover of the Maryland State Medical Journal for July 1962, in which a drug called Librium, "the successor to the tranquilizers," is recommended for a pregnant mother with her first baby, who imagines that she is having birth pains 6 months ahead of time.

You will recall that thalidomide was given in just about this period, early in the pregnancy.

This drug is also recommended for "the surgical patient who sees doom in the frown of a nurse."

Here is another full-page advertisement for Librium in another free medical magazine.

May I interpolate a remark in connection with what has been said here about the generic name for drugs. The remark was made that doctors would not like the generic name; that they would prefer to stay with the trade name of some drug company they trust.

I would dispute that.

I think that every conscientious doctor will be definitely affected by this new law, if it goes into effect; that he will then use the short generic name.

As Mr. Miller, of the United States Pharmacopeia, told you, there are three names. There is a brand name, for example, Thorazine, which I am looking at here on another tranquilizer advertisement; then there is the generic name, which happens to be chlorpromazine, three or four letters more in the word; then there is the long chemical formula, which takes 2 or 3 inches on a page.

The new law, which you are considering here, will give the Food and Drug Administration, at least under Mr. Miller's amendment, standby power, if the U.S.P. does not do it first, to standardize on the short generic name, and I want to say with emphasis that any doctor who will not write three or four more letters on a prescription is not a very good doctor.

He has to be careful that his prescriptions mean what they say. He can be sued for malpractice if they do not. Both he and the druggist have been, and will be, sued for malpractice, if anything goes wrong.

And, finally, it is a very good thing for the doctor to get acquainted with a standard name for these drugs which have so many duplicate trade names.

Here is another tranquilizer advertised in another free medical magazine, which comes out in a newspaper format, the Medical Tribune for August 20, 1962. Here we have a drug called Mellaril, recommended also for women with emotional symptoms in connection with childbirth. It is also for—

tense, nervous patients seen in everyday practice * * * for chronic fatigue, insomia, anxiety, and apprehension, vague digestive disorders, etc.

This is all stated on the advertisement.

I am impressed with that "etc." It just tapers off into the wide, blue yonder where tranquilizers are claimed to be good for everything.

Here is another tranquilizer advertisement, also full page, in the same Maryland State Medical Journal for July 1962. It has a beautiful picture of a happy family, with the caption—

Emotional control regained * * * a family restored * * * thanks to a doctor and "Thorazine" * * * Experience in over 14 million Americans * * * A fundamental drug in both office and hospital practice.

Down at the bottom it also says: "Posed by professional models." They do not want to give the doctor the idea that these handsome people were ever sick, perhaps, or took a tranquilizer.

Let us stop for a minute and take note that many of these advertisements appear in the official journal put out by the State medical society, which is really the local branch of the AMA, and this gives the advertisement a definite degree of official sanction. But the connection lies deeper than that. The facts are that in practically every State in the Union, it is the big drug advertisements which constitute the major financial support for each State medical society journal.

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For example, the Maryland State Medical Journal has 54 pages of advertisements in it this month, and they are almost all of them big drug advertisements.

Furthermore, about half the income of the AMA itself comes from drug advertisements in AMA-controlled journals. This has been true for years.

The reference I can give you on that is from the Journal of the American Medical Association itself, volume 140, page 614.

A similar reference in the same magazine, in the same volume, page 979.

A similar reference supporting this statement I have made, volume 147, page 1246, in 1951.

Will organized medicine ever stop its narrow-minded preoccupation with drugs, far too many of them used precipitantly, displacing sensible procedures, maintaining the patient in a weak and ignorant condition? Does a dog bite the hand that feeds it? There is, of course, a monopoly here, a collusion between organized medicine and the drug industry which strongly suppresses any nonsurgical healing which does not depend on drugs.

Perhaps I may quote to you a statement by Oliver Wendell Holmes, Sr., the physician father of the Justice Holmes who was quoted by one of the pharmaceutical witnesses present before you last Monday.

The father of the great jurist was an equally famous man. He was the codiscoverer of the cause of childbed fever, along with Semmelweiss in Europe, a very great man.

At the time when he was professor of anatomy at Harvard, he made this statement before the Massachusetts Medical Society in 1860.

He said:

> I firmly believe that if the whole materia medica [that is, our drugs] as now used could be sunk to the bottom of the sea, it would be all the better for mankind—and all the worse for the fishes.

I do not mean to say I am a therapeutic nihilist, but I would mention to this committee that our greatest doctors in the past, Hippocrates, who began first with diet and regimen of daily living, then secondly with drugs, and thirdly, if necessary, with surgery; Sir William Osler, probably the greatest physician we have ever had in this country—all such men were very cautious about drugs, and drugs came largely second in their thoughts about what to do in treatment.

Let us also stop and ask how freely can the money flow in this deal from the drug industry to organized medicine?

Mr. Biemiller has already given the figures I was going to give you showing that the profit rates of the drug industry exceed those of all other manufacturing industries in the country.

I would only add that in 1958 the drug industry spent about $750 million for promotion and advertising, compared to a total of $200 million which was the total amount of money available to all the medical schools in this country for their educational program.

The reference for that statement is the AFL–CIO American Federationist for December 1961, page 2 of the reprint.

In this connection, a member of this committee asked Mr. Beesley, president of Eli Lilly & Co., what the relation was between his research and his advertising expense. Mr. Beesley did not know, but page 31 of Senate Report 448, 87th Congress, 1st sesssion, tells us that

for 22 leading drug manufacturers in 1958, research was 6.3 percent and selling expenses were 24.8 percent of the sales dollar. That is, they spent about four times as much on selling as on research.

Here is another full-page tranquilizer advertisement in the Maryland State Medical Journal for July 1962. It shows an alert doctor and two hands of a woman wringing a handkerchief. The caption is:

Safe, continous relief of anxiety and tension for 12 hours with just one capsule without causing autonomic side reactions and without impairing mental acuity, motor control, or normal behavior.

Presumably, any of these last bad things may happen with some other drug company's tranquilizer.

Here is another full-page, big-picture ad in the same journal—and let me say that from what I have seen this is the case in State medical journals all over the country, not just in Maryland—showing a woman selling hats to a customer, with this caption:

"How do you feel lately, Mrs. K?"
"Well, Doctor, some customers still 'get on my nerves' * * * but somehow this doesn't bother me as much * * *. I feel better now and people seem easier to get along with * * *."

And below this conversation—

This could be your "anxiety patient" on trepidone.

Incidentally, let me mention a practical little thing here of interest to anyone who may have a relative or someone on tranquilizers.

Here is a caution as to mixing alcohol, that is, drinking, with the tranquilizer meprobamate, a very common tranquilizer, which I find in the fine print of a big brochure, a big advertising spread, from Wyeth Pharmaceutical Co., which also reached me this week, I think on Monday.

Special care should be taken to warn patients taking meprobamate that their tolerance to alcohol may be lowered with resultant slowing of reaction time and impairment of judgment and coordination.

What I wonder is, if you are taking that stuff, what do you care about warnings? Anxiety is gone. You are tranquil. Let's face it and stop this mercenary deception; the fact is, you are doped.

Here is a full-page ad in Lippincott's Medical Science for August 10, 1962, again, a give-away magazine which is jammed with medical advertisements, showing a wistful, pretty girl with the caption:

If you don't ask her about premenstrual tension * * * she may never know the relief of Cyclex * * * helps you to return the patient to untroubled womanhood.

Cyclex contains several extra bonuses—a diuretic to increase the flow of urine, a special compound to dispel swelling, and meprobamate, the tranquilizer to "quell the psychic tension." This gem is made and advertised by Merck & Co. I forgot to quote what happens if you do not give her the drug: her premenstrual tension, which, let me say parenthetically, is a natural concomitant, to some degree, in every normal woman, this tension "can alter domestic and social behavior * * * complicate other illnesses * * * reduce work attendance and income," if you do not give this drug.

If I may offer a therapeutic opinion of my own, the first intelligent thought when anything goes wrong with the reproductive system

is the diet, just as it is in animals. The question always should be: What is that person eating? And top quality food cuts down and eliminates these troubles better than anything else there is.

But that is not the first thought of the drug advertiser, and, I am sorry to say, of the majority of doctors today.

It is probably not necessary to give more citations. I have 10 more which came out of the same journals, of just about the same caliber. Some of them tell how to take a synthetic male hormone type of thing, one of the exotic creations of synthetic chemistry, and use it for emotional and physical exhaustion, sort of a change from being tranquilized.

There are also special new drugs to shake up the metabolism in most complex manners so that a tennis elbow feels better.

All these medications usually constitute unscholarly meddling with delicate body mechanisms.

Here is the tennis elbow in a full-page advertisement.

Mr. Chairman, it seems to me that the kind of advertisements I have been reading are either exceedingly childish or degenerate, or both; and that a more strict control of drugs and their labeling in advertising is imperative.

H.R. 11581 is a step in the right direction. I think the efficacy phrases should be taken out, as Mr. Klump testified so eloquently, because, as has been pointed out by many witnesses, these phrases give great power to one man which even a group of men would not be wise enough to merit, so intricate is the human machinery.

There is never any question about our spectacular drugs. It is only those with more subtle action which work only under special circumstances and conditions, and we must we chary of setting a precedent of one man deciding and dictating that a drug is or is not efficacious in the complicated human animal.

On the other hand, we can achieve very much the same ends by a much better method.

For example, the bill would be greatly strengthened if an amendment were added stipulating that patients must give their written consent before being experimented on with a new drug not approved by the FDA.

The public will then know what is going on, just as they know more or less what to expect when they sign the standard hospital operation permission form. Both parties will stop and think a moment, which is just as it should be.

Of course, such written permission to receive a specific drug will act as a check on the testing of new drugs, and the pharmaceutical companies will not like that, but that is just what the public needs now, and I venture to say, will always need, in order to hold down the thoughtless promotion of drugs.

There will be no appreciable increase of paperwork, if the patient signs his name to show that he has been informed that such and such new drug will be given to him, because the doctor already has a sheaf of forms to fill out and sign himself for each patient to whom he gives a drug under test.

If a patient is not told that an experimental drug is being used on him, that patient is in the dark.

When the labeling which accompanies a drug, including its advertisement, misleads the doctor, that doctor is in the dark.

The American way is not to dictate any more than can be avoided what a man must do, but, rather, to turn on the light so that he can see what he is doing.

Mr. Chairman, I have a brief remark to make at the end of my prepared testimony in which I would like to respond to a point which you have made with clear emphasis on two occasions that I know of, Monday and today, to the effect that no testimony has been given here that H.R. 11581 would prevent the thalidomide type of accident.

I would like to answer your remark on that by saying that I believe this new bill would greatly reduce the risk of such an accident for the following reasons:

First, it lengthens the time over which the Food and Drug Administration can consider a new drug; and the deluge of drugs which descends upon the FDA, which even Dr. Klumpp referred to in his testimony as a terrible deluge of drugs, that would be reduced.

Much time is required to test a drug. It is amazing how long one should study these things and how many animals should be used; by slowing up the process the FDA can do a better job.

Secondly, as I understand it, the new bill puts a burden of proof upon the drug manufacturer to demonstrate that his new drug is safe.

It would not receive approval by default. As things stand now, unless the FDA comes up with adverse evidence within 60 days, the drug is automatically accepted.

That, again, will slow up things and give time for good work to be done by the FDA.

Thirdly, the amendment which I have mentioned above requiring revelation to the patient that he is participating in an experiment on a new drug will also slow up the deluge, and give time for a more scholarly decision.

If people know that they are taking an experimental drug, any abnormality which the patient experiences will cause him to report it, perhaps months ahead. He can be an intelligent guinea pig, if you will, and not an absolutely helpless, victimized person who has been given this drug as in the thalidomide case by some obstretician who never told the patient what she was getting.

So the warning would go out far quicker to cut off the supply to other patients of a dangerous drug.

For those three reasons, and by enforcing labeling, which is perhaps not so much a part of this bill, I do believe, Mr. Chairman, that the chance of a thalidomide type of accident would be greatly reduced.

We cannot entirely eliminate accidents in this field, any more than we can in air travel, but we can do much better than we have been doing.

Thank you, Mr. Chairman, for the privilege of giving you my testimony.

The CHAIRMAN. Doctor, the question I raised a couple of times was, in no way, questioning the fact that Dr. Kelsey had done a magnificient job, as has been so well and appropriately recognized.

The point that I have raised is that under present law, any such type of drugs could be denied clearance by the Food and Drug Ad-

ministration within the time to act upon it, and then the matter goes to a hearing.

That was the point that I have tried to make.

I have not at any time indicated that the provisions of this bill would not give more time for consideration. It may be that 180 days would be more sufficient time to make such a determination than 60 days, but under this provision precisely the same thing is involved, except, instead of having 60 days, you have 180 days.

You have got to make a decision and then go to hearing, if necessary.

Are you an M.D.?

Dr. ROBINSON. Yes, sir, I am.

The CHAIRMAN. In private practice?

Dr. ROBINSON. Yes.

The CHAIRMAN. You have given the committee an interesting discourse here which certainly is a wide variation from anything we have had.

Obviously, it is a thought that should be kept in mind.

There may be something to what you say.

I think probably it might be a good idea to have the drug people comment on this. I imagine they would probably welcome that opportunity, even though I am not suggesting that these hearings should go on and on.

But there is one thing in your statement that, to me, is a rather serious accusation, and even if the trend of thought of the American people, as you have described here, is questionable in the minds of other people, it is a very serious thing when you say that "There is collusion between organized medicine and the drug industry."

If that be true, I think that some serious consideration should be given to it. I simply cannot believe it myself. You are a doctor, and I assume you belong to the American Medical Association, do you not?

Dr. ROBINSON. I belonged for many years.

The CHAIRMAN. I assume you belong to your local medical society?

Dr. ROBINSON. Oh, yes, I belong to my local, county, and State medical associations. Aside from any other reasons, without these memberships I could not practice in hospitals, obtain standard malpractice insurance, or participate in Blue Cross or Blue Shield. But I disagree so much with what the A.M.A. does that by choice I have not belonged to the A.M.A. in recent years. I am not alone in that respect, for as the Montgomery County Medical Society Bulletin points out in its issue of August 1962, p. 239, "* * * a good many doctors do not belong to or believe in their own organization" (the A.M.A.).

The CHAIRMAN. The doctor is so important to the life of the individual and the family. I suppose the doctor probably is more intimate with family life than perhaps anyone else. And if the medical profession is putting itself in the position of being in collusion with the drug industry to commercialize on the lives of the American people, that is a pretty serious charge.

Dr. ROBINSON. Yes, sir.

May I say that some things acquire respectability through age alone, and for really many years the drug industry has contributed large sums, one-half the income of the AMA comes from the drug companies—you can find it in the AMA financial statement—and, as was

said earlier here today by, I think Dr. Miller of the U.S.P., up until 1955 the AMA made some effort to control the quality of drug advertisements in its journals.

But in about 1955 the AMA more or less threw in the sponge. It was just too much for them.

So far as the AMA being influenced by drug interests, it is like the old story from the South that if you will tell me where a man gets his corn pone, I will tell you what his politics are.

I think that does apply to the AMA. It cannot help but be strongly influenced by the pharmaceutical industry.

The CHAIRMAN. Doctor, I have never come to the belief that the intricate lives of the American people mean so little to physicians that, when you get down to it, the relationship is more basically commercial than it is to do something for humanity.

Any further questions?

Mr. ROBERTS. Doctor, one thing I would like to ask.

How easy is it to get some of the commonly known tranquilizers—take Equanil, Miltown—once a prescription has been given?

I mean are most of these refillable without another prescription?

Dr. ROBINSON. I have prescribed a tranquilizer only once, about 8 years ago so I am not sure how careful doctors and druggists are about this nowadays. The chances are that they are not refillable without the doctor's permission. But he may phone the druggist, or write on his prescription blank, "Do not refill at all," "Refill once," "Refill three times," or "Refill as needed," so there is plenty of leeway here.

Mr. ROBERTS. That is all.

Mr. MOSS. Mr. Chairman.

I want to take the opportunity to compliment you, doctor. It is to me a very refreshing thing to have an individual come here and from a background of professional knowledge undertake to share with the members of this committee his convictions gained from experience, and who, I might add, is sufficiently worldly to recognize that the appearance of a doctor here under these circumstances takes a small measure of courage, at least. I think, for your interest, demonstrated by your appearance, that you are certainly deserving of a degree of congratulation, and I certainly extend it to you.

Dr. ROBINSON. Thank you, sir.

Mr. Chairman, may I say that I agree with you absolutely that there is not an overwhelming commercial flavor to the practice of medicine.

There is not.

All that I was pointing out is that there is an undue influence from the pharmaceutical industry which has taken us away from our highest principles of Hippocrates, Sir William Osler, and Oliver Wendell Holmes, and we have gone too far in this business of drugs, well shown by the advertisements which I have read. Our predicament is tied up with the financial connection between the AMA and the drug industry.

I should add that those things develop so gradually that one drifts into it.

We have now generations of doctors who have been indoctrinated too much in the way of drug therapy, and that sort of thing progressively permeates and colors the situation imperceptibly without any

criminal intentions on the part of anyone. I was speaking out against that trend.

The CHAIRMAN. Doctor, I agree with Mr. Moss. It takes a lot of courage to do what you have done today, and if these things are true, as I have already said, it is a very serious situation indeed. I notice that you have been teaching at Vanderbilt Medical School in Nashville, the University of Pennsylvania Medical School, and if what you have just said is true, I think it is certainly a reflection on our medical institutions in not training our doctors in the proper concept. If we ever get to the point in this country where we cannot depend on the doctor to protect the lives of the people, then I think you are going to find some real revolution taking place in the practice of medicine, if the people come to that realization.

Mr. FRIEDEL. Mr. Chairman?

The CHAIRMAN. Mr. Friedel?

Mr. FRIEDEL. May I ask one question?

Doctor, have you ever made a written or verbal protest to the AMA?

Dr. ROBINSON. Yes, indeed, I have.

Mr. FRIEDEL. Once, twice, many times? When was the last time?

Dr. ROBINSON. Well, sir, it is a long story, but I had a major battle with the AMA, lawsuit and all the rest, at the time when I was out in Washington State and the AMA and its local societies were monopolizing medical practice through so-called medical bureaus.

The AMA and its State societies were arranging for the local doctors actually to own and operate these bureaus which were, in fact, simple commercial insurance companies, a very radical development that took place in a State, Washington State, which at that time was quite radical in its welfare programs.

The State nearly went bankrupt in giveaways in medical care.

So I had quite a battle with them out there because I observed that the system of doctors employing themselves in medical insurance companies was leading to decay in the profession. And so I have been very much in opposition to the AMA beginning about 10 years ago.

Mr. FRIEDEL. That is all.

The CHAIRMAN. Doctor, thank you very much for your presentation.

Dr. ROBINSON. Thank you, sir.

(The supplemental statement of Dr. Miles H. Robinson follows:)

SUPPLEMENTAL STATEMENT OF MILES H. ROBINSON, M.D., IN SUPPORT OF H.R. 11581, AUGUST 28, 1962

Mr. Chairman and members of the committee, a few days after I had the privilege of appearing before you on August 22, the Saturday Review of Literature, issue of September 1, 1962, was published. It contains a remarkable article by the science editor with many new facts bearing on the drug situation which I believe the committee would find useful to have at hand as it weighs the provisions of H.R. 11581.

For example, the article cites from the files of our Food and Drug Administration cases of concealment for as long as 5 years by drug companies of deaths caused by various new drugs (p. 40). It reveals the FDA figure of 19,822 Americans who took the tranquilizer, thalidamide (p. 38). It describes how U.S. Food and Drug Commissioner Larrick waited for 6 months and a public uproar before sending out his agents to round up what remained of Merrell's experimental pills in physicians' offices throughout the country. Germany had taken

thalidamide off the market 6 months before Mr. Larrick acted, as soon as that country confirmed the drug's complicity in birth of malformed babies.

The thalidamide story which has appeared in the press in necessarily scattered form as the details developed, is chronologically and adequately summarized in the Saturday Review article.

The whole picture of drug experimentation and promotion is brought into sharp focus, and further supports the testimony which I gave to the committee. For these reasons, I earnestly hope that you will include this article, in full, as part of my supplemental statement. If this cannot be done, I hope that the excerpts which I have marked can be included.

Enclosed is a copy of the magazine in question.[1]

The CHAIRMAN. Mr. Clinton R. Miller, who will be the final witness. Mr. Miller, you may proceed.

STATEMENT OF CLINTON R. MILLER, ASSISTANT TO THE PRESIDENT OF THE NATIONAL HEALTH FEDERATION; ACCOMPANIED BY CHARLES ORLANDO PRATT, ATTORNEY

Mr. MILLER. Thank you, Mr. Chairman.

I am accompanied today by the legal counsel of the National Health Federation, Mr. Charles Orlando Pratt.

Mr. Chairman, for the record, I am Clinton R. Miller, assistant to the president of the National Health Federation. Our main office is 709 Mission Street, San Francisco, Calif. Our Washington office is at 1012 14th Street NW., Washington, D.C.

The National Health Federation is a rapidly growing national organization, composed of thousands of members who believe in freedom of choice in matters of health where the exercise of that freedom does not endanger the health or safety of another, and thereby deny him an equal freedom.

In matters of health, the professional and commercial interests involved have been well organized for many years. The Pharmaceutical Manufacturers Association and the American Medical Association have represented their members' commercial interests extremely well, as evidenced by the profits of the former, and the top professional income position of the latter. Where this position has been gained within the framework of freedom and fair competition, we applaud and support their success. To the extent, however, that it has been gained as a monopoly, by suppressing freedom of choice, information, and competition, we condemn and oppose them.

In the present bill we find ourselves in both roles. We support their reasonable requests for certain language changes in the bill which would prevent giving unlimited, arbitrary powers to Government. One Dr. Henry Welch is too many.

We, on the other hand, point out that the AMA has been found guilty in the past of a criminal conspiracy to monopolize the healing arts. If the drug industry is guilty today of monopoly control, then they should be prosecuted under the laws that forbid trusts. The laws presently on the books are adequate for that.

In matters concerning their health, the average American has not been so well organized and represented as the commercial interests. Consequently, he has had very little protection from certain monopolistic forces in the field of health which have run rampant in America

[1] The material submitted by Dr. Robinson may be found in the files of the committee.

for many years. The National Health Federation was formed to fill this need. While no two people in America have identical beliefs in respect to the best approach to health, they all have one belief in common, and this is that every person should have the right of freedom of choice in what is done to his body. We weigh all proposed legislation on this scale, and believe that freedom of choice for the well-informed individual is the safest, fairest, and wisest position that a lawmaker can take.

MEDICAL EXPERIMENTATION WITH DRUGS WITHOUT PATIENT'S KNOWLEDGE OR CONSENT

We wish to focus the committee's attention on what we feel is the most glaring loophole in our present law: the absolute lack of any effective control of investigational drug experimentation on involuntary human guinea pigs. The fact is dawning on Americans that they have been, and are being, subjected to extremely hazardous and dangerous medical experiments on their bodies without their knowledge or consent. This is increasing on a vast scale, unprecedented in history.

Furthermore, there is nothing in the instant bill, H.R. 11581, to recognize, prevent, or correct this specific situation. No person should be denied the right to know that he is participating as a human guinea pig in a medical experiment, and that he is taking an experimental drug with unknown side effects.

THE PROPOSED NATIONAL HEALTH FEDERATION AMENDMENT

We respectfully urge that a new section be added under title I, part A. We suggest that it contain the following:

NOTIFICATION OF EXPERIMENTAL DRUG USE

The following statement must be signed by a doctor's patient, or the patient's legal guardian, before he may be given a new, experimental drug:

I have been advised that _____, an experimental new drug, as yet unapproved by the Food and Drug Administration, is to be administered to me for the purposes of testing its usefulness, safety, and/or possible harmful side effects. Signed by the patient or the patient's legal guardian.

The Washington Post of Sunday, August 19, 1962, carried the following information:

The FDA surveyed the investigational use of thalidomide in the United States, finding that, as of August 6, 3,372 women of childbearing age were known to have received the drug.

This points out the unlimited right to experiment on humans without their knowledge or consent.

Here are some hard-to-believe facts:

1. Americans will soon know that under the present and proposed law, there is no limit as to how long one can investigate with a new drug.

2. Under the present and proposed law, there is no requirement that the doctor even tell a patient that he is being used as an involuntary human guinea pig.

3. Under the present and proposed new law, there are no Federal requirements—and I will repeat this—there are no Federal re-

quirements that a doctor keep a record of any patient who receives an experimental drug.

4. Under the present and proposed law, there is nothing that prevents a doctor from charging a patient for a new, experimental drug.

5. Under the present and proposed law, there is nothing to prevent the drug company from charging the doctor for the experimental drug.

6. Under the present law, there is nothing to prohibit a drug company from changing to some degree the formula of thalidomide, and starting all over again as an experimental drug under a new name. Indeed, there is evidence that this is happening today.

7. Finally, where a drug company and a doctor may both charge for an experimental drug given to an involuntary human guinea pig, where they do not have to notify any governmental agency of their intent to start testing, or of the failure of any such tests, and where there is no limit to the number or length or extent of such tests, we have a loophole in which these commercial interests can operate business as usual without the knowledge, control, or consent of either a patient or his government.

The great uneasiness in America today is because at the same time that we are giving medals to FDA officials for keeping an untested drug off the market, the hard and stubborn fact remains that for all practical purposes the drug was on the market in this country, and was given to thousands and thousands of unsuspecting Americans without their knowledge or consent.

The National Health Federation amendment would at least require that this testing be done with the knowledge and consent of the individuals being used in the experiment. This is the very minimum that Americans can expect.

The Nuremberg war trials did not challenge the matter of testing with human guinea pigs. It did emphasize and establish that voluntary consent is the first prerequisite for human experimentation.

When convicts or political prisoners are used in America for human experimentation, it is done with their consent, and they may withdraw from the experiment at any time they choose. This same right should be afforded the rest of America.

To preserve the time of this committee, the balance of the National Health Federation testimony will be submitted in our written statement.

Thank you.

The CHAIRMAN. Very well.

You may submit the additional information for the record.

(The statement referred to is as follows:)

WRITTEN STATEMENT OF CLINTON R. MILLER, ASSISTANT TO THE PRESIDENT OF THE NATIONAL HEALTH FEDERATION

In my statement before the committee, I mentioned the Nuremberg war trials, and the rules that were set down as a result of these trials, concerning human

medical experimentations. The Tribunal's judgment, rendered August 19, 1947, of the Nuremberg medical trial gave the following judgment on:

PERMISSIBLE MEDICAL EXPERIMENTS ON HUMANS

"The greatest weight of evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical, and legal concepts:

"Nuremberg rule No. 1. *The voluntary consent of the human subject is absolutely essential.* [Emphasis ours.] This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. The latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

"The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

"Nuremberg rule No. 2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

"Nuremberg rule No. 3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated result will justify the performance of the experiment.

"Nuremberg rule No. 4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

"Nuremberg rule No. 5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

"Nuremberg rule No. 6. The degree of risk to be taken should never exceed that determined by the human importance of the problem to be solved by the experiment.

"Nuremberg rule No. 7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

"Nuremberg rule No. 8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

"Nuremberg rule No. 9. During the course of the experiment the human subject should be at liberty to bring the experient to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

"Nuremberg rule No 10. During the course of the experiment the scientists in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of good faith, superior skill, and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability or death to the experimental subject."

A valuable reference book on the instant subject is, "Experimentation in Man," by Henry K. Beecher, M.D. It is published by Charles C. Thomas, 301–327 East, Springfield, Ill. The Library of Congress Catalog Card No. is 58–14065. The National Medical Library call No. is, W 50 B414e, 1954.

The National Health Federation amendment has only included part of the Nuremberg Rule No. 1. "The voluntary consent of the human subject is absolutely essential." There were 23 defendants in the Nuremberg Medical War Trials. Fifteen were found guilty. Seven were hanged. Four of the seven were physicians. It was freely admitted that in America there were human medical experiments similar to those of the accused war criminals but they were all performed with the consent of the human guinea pig. It was the failure to get voluntary consent that made the act of human medical experimentation criminal. The National Health Federation would like to see the 10 Nuremberg rules established as the standard to govern all human experimentation.

EXPERIMENTATION WITH HUMANS—AMERICAN STYLE

In a press release for Thursday, August 23, 1962, the Food and Drug Administration disclosed some shocking aspects of the present uncontrolled status of experimental drugs in America. The following quotes are from this press release by FDA officers Janssen and Brooks:

"Thalidomide was never approved for sale in this country, but under the law the manufacturer could distribute thalidomide tablets to doctors for clinical investigation. On this basis, the FDA survey shows more than 2,500,000 tablets were distributed to 1,267 doctors."

CLINICAL INVESTIGATION WITHOUT RECORDS

Lest any Congressman assume that the fancy words, "clinical investigation" imply a tight, safe, scientific, well-controlled and documented use of potential deforming or lethal drugs, consider the following from the same press release:

"FDA disclosed that 410 out of 1,168 doctors interviewed by its inspectors had at that time made no effort to contact patients to whom they had given the drug. Many of the 410 felt it was not necessary because of the time lapse, or they had no records to indicate which of their patients had received the drug.

For emphasis, we shall repeat that last statement—"or they had no records to indicate which of their patients had received the drug." Is this the picture that was painted by witnesses for the Pharmaceutical Manufacturers Association to members of this committee? Indeed not. Consider that over one-third of these "clinical investigators" either had no records, or had made no effort to contact patients. Would it be an improper function of Government to ask that the list of these 410 doctors be made public to protect their unsuspecting patients?

SO THIS "CLINICAL INVESTIGATION"?

Further incredible disclosure of the method of "clinical investigation" is in the following paragraphs from the same press release:

"A doctor in Kansas City, Mo., gave 50 tablets to a male patient who passed some of them on to his married daughter. She took the drug during the early stages of pregnancy and is due to deliver by October 1962. The case is being followed up."

FEATHERS IN A HURRICANE

For tightness of scientific control, this disclosure is hard to beat (also from the same press release):

"Six doctors donated supplies of thalidomide to religious groups for charitable distribution overseas and are unable to trace the present location of these drugs."

The FDA press release continues:

"Records furnished by the firms show that 2,528,412 thalidomide tablets were distributed to doctors for investigational use. They varied in strength (quantity of the active ingredient) from 12½ to 200 milligrams. Lesser quantities of liquids and powders containing the drug were also distributed.

"More than 50 percent of the doctors interviewed had no record of the quantities returned or destroyed pursuant to the manufacturer's instructions. *There is no way of knowing the amounts actually returned or destroyed,* FDA said. [Emphasis ours.]

"Most of the doctor-investigators said that they had received the manufacturer's advice in March 1962 to stop using the drug, but 85 said they were not warned of adverse reactions and 42 said they did not get any message from the manufacturer. The notice to discontinue was given by letters, with followup

phone calls and visits by detail men beginning in March and continuing through July 1962.

"Doctors interviewed reported that 19,822 patients had received thalidomide. Of these, 3,760 were women of childbearing age, of whom 624 were reported as pregnant. *According to the doctors* [emphasis ours], most of the pregnant patients got the drug in the last trimester of pregnancy or just prior to delivery. There are reports of 21 women who have not delivered. Three of these are reported to have received the drug in early pregnancy.

"Three cases of abnormalities have been reported in offspring patients who took thalidomide distributed in the United States, FDA said. * * *

"When asked if they had signed a statement on their qualifications, required by FDA regulations to be obtained by the manufacturer, 640 doctors stated they had signed such statements but 247 said they had not. Others said they could not remember or did not answer the question."

The release closes by updating figures in the August 7, 1962, progress report on FDA's survey of the investigational use of thalidomide in the United States.

	Aug. 7	Aug. 21
Number of pregnant women reported to have received the drug	207	624
Number of doctors reported as investigators or users of thalidomide	1,248	1,267

There is no explanation offered as to why an increase of 1½ in doctors reporting should increase by 300 percent the number of pregnant women reported to have received the drug.

One has the uncomfortable feeling in reading these reports that someone is trying to keep a lid on something.

In summary, no person should be denied the right to know that he is participating as a human guinea pig in a medical experiment, and that he is taking an experimental drug with unknown side effects. We respectfully urge this committee to amend H.R. 11581 to include this safeguard.

The CHAIRMAN. Any questions, Mr. Friedel?

Mr. FRIEDEL. At the proper time I probably will propose an amendment to the committee.

Mr. MILLER. Thank you very much.

The CHAIRMAN. Mr. Moss?

Mr. Moss. I have no questions, Mr. Chairman.

I might state that, in general, I agree with the proposal that there should be some agreement on the part of a patient before they are subjected to some of these very radical new compounds.

Mr. MILLER. Thank you, Mr. Moss.

The CHAIRMAN. Thank you, Mr. Miller.

This will conclude the hearings for today.

The committee will adjourn until 10 o'clock in the morning.

(Whereupon, at 4:50 p.m., the hearing was adjourned, to reconvene at 10 a.m., Thursday, August 23, 1962.)

DRUG INDUSTRY ACT OF 1962

THURSDAY, AUGUST 23, 1962

HOUSE OF REPRESENTATIVES,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The committee met, pursuant to recess, at 10:15 a.m., in room 1334, New House Office Building, Hon. Oren Harris (chairman of the committee) presiding.

The CHAIRMAN. The committee will come to order.

Yesterday Mr. Benjamin G. Habberton testified, and, in response to a question, he discussed the extent of the interest of the dairy industry and its products in the factory inspection provision of this bill.

This morning I have a letter from Mr. Habberton which he feels would be further responsive to the question raised at that time.

Therefore, the letter will be included in the record at the appropriate place.

(The letter referred to was inserted following the testimony of Mr. B. G. Habberton on p. 456.)

The CHAIRMAN. For the record, Mr. R. E. Horsey, of Givaudan Delawanna, 321 West 44th Street, New York, may include a statement at this point.

(The statement referred to is as follows:)

STATEMENT OF ROBERT E. HORSEY OF GIVAUDAN-DELAWANNA, INC., ON H.R. 11581

I am Robert E. Horsey, vice president of Givaudan-Delawanna, Inc., whose executive offices are located in New York City. I have been employed by this company for the past 20 years. This company is a wholly owned subsidiary of the Givaudan Corp. These companies are incorporated in the State of New Jersey. Our plant is located in Clifton, N.J., and in our New York City location we maintain our perfume laboratories.

My presence here is to voice our opposition to only the strengthening of factory inspection authority provision (section 201) of this bill.

We object to this increased inspection authority because, if enacted, it would jeopardize the very foundation of our business, namely the trade secrets which include our valuable formulas for perfume bases and unique processes for manufacturing perfume materials.

To understand why these trade secrets are such a valuable asset, it is necessary to explain our company's activity and its role within the fragrance industry and its relationship to the cosmetic industry.

Our companies are engaged in the manufacture and sale of perfume materials and compositions made from perfume materials which, for the purpose of this statement, we shall call perfume bases. These perfume materials and bases are sold to manufacturers of perfumes, colognes, cosmetics, soaps, and many other consumer products. Our companies were established in the United States in 1924. Prior to this time Givaudan products were imported into the United States and, therefore, have been supplied for these uses since the early 1900's.

During the past 38 years the scope of our operation has grown from a modest 80 to 500 employees and the plant value increased by twentyfold. We manufacture approximately 500 different perfume raw materials, and currently supply

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several thousand different perfume bases to the cosmetic and other consumer products manufacturers.

At the outset, I would like to emphasize that we sell only to manufacturers, and our problems are not the same as those of the cosmetic industry. Therefore, we do not believe we should be subjected to the same regulation.

Givaudan initially entered the perfume industry by pioneering in preparing synthetically some of the constituents found in the odorous oils of plants and flowers. This came about from research into the constituents of natural products, synthesizing them in the laboratory, and finally developing processes which could produce, economically, commercial quantities.

It was quite a logical step to try to use these synthetically prepared materials to duplicate the elusive fragrance of the natural flower oils. Through the imaginative, creative, and artistic ability of our perfumers, we were successful in combining synthetic and natural substances into redolent creations. Many other original creations are produced each year.

The sale of these perfume bases constitutes a large part of our sales volume. An appreciable number of them have been sold continuously since the earliest days of our business. In spite of all the modern scientific tools, they have defied duplication by others. Obviously, access to formulations would make the task of duplication a simple one and, for this reason, we have, within our company, an elaborate security system whereby only a few responsible individuals have knowledge of the complete composition.

Equally important and valuable are the many unique processes developed to make perfume raw materials. The chemistry involved is fairly well known, but to produce, synthetically, perfume materials which have fine odor quality is not so simple. The fine quality and uniformity of the ones we produce are dependent on the processing skills and processes we have developed over the years.

In relation to the cosmetic and other consumer product manufacturers, I am sure you can appreciate that the public acceptance of their products is greatly influenced by the fragrance. The fragrance in many cases is as valuable as their trademarked brand names. For this reason, manufacturers are also anxious to preserve the secrecy of the fragrance for they have many dollars invested in these valuable franchises. Consequently, there is a great confidential business relationship between the fragrance supplier and customer.

The factory inspection (sec. 201 of H.R. 11581) has been proposed to better protect the public health. We, too, have a keen interest in protecting the public health, but we know of no evidence which indicates that perfume raw materials or perfume bases are endangering it. Neither can we understand how the public health could be better protected by broadening the factory inspection.

No arguments have been presented by the administrative agency proving that the present legal procedures for compelling disclosure of information in relation to a violation are inadequate.

We cannot see how the unlimited examination of our processes and formulas can better protect the public health, but we can foresee the potential damage to our business when any inspector would have the right during any inspection, routine or otherwise, to copy and take with him any or all our trade secrets, including formulas, processes, and confidential business relationships.

We have had to deal with the security problem of our formulas and processes since the inception of our company. For this reason we cannot treat lightly or rule out the possible inadvertent disclosure or deliberate misuse of confidential information by FDA inspectors. This is not an accusation of the FDA personnel, but over a period of years we could be subjected to a significant number of inspectors who may or may not remain in the employment of the agency. We do know that the danger of leakage of confidential matters is in direct proportion to the number of individuals possessing such knowledge.

If the administrative agency deems it necessary to strengthen the factory inspection authority for the control of safe drugs, we cannot agree this is a reason for extending it to other industries. We do not know the problems of the drug industry, but we are certain greater inspection of our establishment is not necessary. In fact, to the best of our knowledge, no need has been shown for increased inspection privileges or that the present inspection authority is inadequate in preventing the misbranding and adulteration of cosmetics.

In behalf of our company and others in the fragrance industry, we urge the committee to give careful consideration to our unusual dependence on protecting

our trade secrets and the irreparable harm we would suffer through their loss. We strongly recommend that section 201 in H.R. 11581 be limited to drugs, since that is the main scope of the bill. If, for some reason not obvious to us, this is not feasible, then we recommend a revision of section 201 be made which would exempt perfumes and fragrances from this broad factory inspection authority.

The CHAIRMAN. It is expected that the hearings on this proposed bill will conclude perhaps today, if not tomorrow. We have a number of witnesses yet to be heard, and we will undertake to get to them during the day.

If the witnesses and the members of the committee will keep this in mind, I think it can be concluded today.

At the conclusion of these witnesses the record will be kept open for a period of 5 days, and under the usual procedure the committee will receive any additional statements that anyone might desire to file. All statements pertinent to this proposed legislation will be received during that period.

The first witness this morning will be Mr. Philip F. Jehle, Washington representative and associate general counsel of the National Association of Retail Druggists.

Mr. Jehle?

STATEMENT OF PHILIP JEHLE, WASHINGTON REPRESENTATIVE AND ASSOCIATE GENERAL COUNSEL OF THE NATIONAL ASSOCIATION OF RETAIL DRUGGISTS; ACCOMPANIED BY JOSEPH COHEN, ASSOCIATE WASHINGTON REPRESENTATIVE

Mr. JEHLE. I am Philip Jehle, the Washington representative and associate general counsel of the National Association of Retail Druggists. As you know, the NARD is a small business organization having a nationwide membership of more than 36,000 community drugstore owners. It is both an honor and a duty for the NARD to speak for these family pharmacists on all Federal legislative matters affecting their professional and competitive interests. Accompanying me this morning is Joseph Cohen, associate Washington representative of the NARD.

I deeply appreciate your kindness in granting this opportunity to offer the views of the NARD on H.R. 11581, the bill amending the Food, Drug, and Cosmetic Act. I do understand the many practical problems involved in arranging to hear the numerous witnesses desiring to testify on the proposed legislation. Accordingly, I shall try my best to keep my presentation this morning brief and to the point.

At the outset, Mr. Chairman, I would like to emphasize that the provisions of H.R. 11581 are directed mainly at the pharmaceutical manufacturers; that is, toward those engaged in the research, development, and production of prescription medications. Only in a few instances do the provisions of the measure have a direct application to those engaged in the retail distribution of prescription drugs. This being the case, our comments on the proposed legislation will be limited to those provisions which would have a significant impact upon retail pharmacy. Not having any drug manufacturers as members, the NARD does not presume to speak for them on legislative matters or

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otherwise. We speak only for our 36,000 independent retail pharmacist members.

As briefly as possible, our comments on H.R. 11581 are as follows:

(A) AMPHETAMINE AND BARBITURATE CONTROLS

In general terms, these provisions of the bill are intended to facilitate efforts of the Federal Food and Drug Administration to check illegal trafficking in amphetamines and barbiturates. With this praiseworthy objective, all concur including the NARD. Yet, such a goal, however commendable it may be in itself, should not be used to justify a move by Government officials to obtain more enforcement authority than is actually needed and which may be abused as a result. Specifically, I am referring to that provision which would enable FDA agents to inspect, among other business and professional records, the pharmacist's prescription files. For years, FDA officials have been trying in one way or another to get authority to search the prescription files of the retail pharmacist. Until now, Congress has consistently withheld such authority on grounds that a case for granting it has never been made. This fact, however, has had but little influence upon those intent upon assuming new and broader powers for themselves.

In the view of the NARD, prescription file inspection authority as it is being sought in H.R. 11581 should be denied the Federal Food and Drug Administration for the following reasons:

(1) It is unnecessary: For many years, the inspection of prescription files, including those relating to amphetamines and barbiturates, has been performed competently and diligently by appropriate State authorities. This is true in every State of the Union. It would be both unwise as well as frightfully expensive for the Federal Government to duplicate the fine enforcement work of State authorities. This committee should certainly find out from the appropriate State officials whether they are doing an effective job of inspecting pharmacists' prescription files.

(2) Unaccountably, the prescription file inspection authority being sought in the proposed legislation would cover all pharmacies while, at the same time, expressly exempting all medical practitioners, many of whom do a rather large business in the dispensing of prescription medications. Frankly, the NARD and its members are unable to understand why such unjust discrimination against the profession of pharmacy should exist in this bill. No satisfactory explanation has ever been offered.

(3) FDA agents already have sufficient legal authority to investigate all records including prescription files of any person who may be illegally handling or disposing of amphetamines and barbiturates. Where a search warrant for such investigation becomes necessary, it may be easily obtained by FDA agents. Once probable cause has been shown, the warrant may be issued and the search may begin. Every competent, experienced law enforcement officer would tell you that he has no trouble getting a search warrant when he needs it. I am also confident he would let you know that he is satisfied with existing procedures for obtaining it and has no need of legislative

shortcuts. He is happy to perform his job according to the Constitution.

For this committee to make it abundantly clear that H.R. 11581 does not authorize carte blanche prescription file inspection authority for amphetamine and barbiturate irregularities, a simple amendment may be made. Change line 6 of page 27 of H.R. 11581 to read as follows: "in subsection (b) (3) and (4)" et cetera.

The addition there is (3). That will make it clear that the exemption applies to the profession of pharmacy as well as to the profession of medicine.

(B) PRESCRIPTION DRUG ADVERTISING

Simply stated, these provisions of H.R. 11581 would require all prescription drug advertising, regardless of type of publication or other medium involved, to set forth clearly and fully such "basic information" as the medication's (*a*) quantitative analysis and generic name; (*b*) contraindications, and (*c*) side effects. The apparent purpose of such "affirmative disclosure" is to assure physicians of receiving all relevant information concerning the safety and efficacy of advertised prescription drugs.

In judging the merits of these provisions, our main concern has been the impact they would have upon the advertising of prescription drugs to the Nation's retail pharmacists. For, whether intentional or not, the informational requirements would apply to prescription drug advertising in our NARD journal and to the numerous State and local pharmaceutical association publications. By no means should it be thought that the scope of the challenged provisions would be limited to medical journal advertising.

Of course, the NARD understands and is sympathetic to H.R. 11581's avowed purpose of making certain physicians are fully informed concerning the unfavorable as well as the favorable aspects of all prescription medications. In fact, we are sure this is a universally supported objective. At the same time, however, we do not believe H.R. 11581 is an appropriate means of accomplishing such a laudable purpose. Among the major considerations militating against the proposed legislation in this regard are the following:

(1) It would be unnecessary: Physicians obtain information about the therapeutic effects of prescription drugs from recognized professional authorities, such as the Drug Index and the Merck Manual. Pharmacists, too, have their professional sources for such information. They use such sources as the United States Pharmacopoeia, National Formulary, and the United States Dispensatory.

No reputable physician would ever prescribe a medication that he know about only through advertising seen in a professional journal. Nor would a responsible pharmacist base his knowledge of the purpose, safety, efficacy, and dosage forms of a prescription drug upon the manufacturer's advertising statements. To even suggest that physicians and pharmacists would so conduct themselves seems almost scandalous.

Also to be noted in this regard are the FDA administrative regulations which became effective in March of this year requiring drug manufacturers to attach to or enclose with their prescription medicines and devices brochures (package inserts) containing all necessary

information for the sale, effective use of such drugs and devices. Such brochures or package inserts are filed by pharmacists for use in advising physicians of the therapeutic properties and effects of prescription drugs and devices. Through such means, physicians have another ready, competent source of technical information and advice.

(2) It is impractical: In effect, these provisions would compel prescription drug advertisers to ground their advertising copy upon their new drug applications and supporting materials. Although such extensive technical data could probably be condensed somewhat and the salient points extracted for advertising use, the process would be complex and extremely time consuming. As a result, many drug manufacturers would find such advertising inadvisable. Many others would shy away from the formidable legal risks involved in passing upon "full disclosure" or the propriety of the relative emphasis given favorable and unfavorable therapeutic aspects of a particular drug.

Drug advertising in professional journals is primarily for "reminder" purposes. It is not intended to be educational, except in a very general way. Drug advertisers recognize the virtual impossibility of using an advertisement to explain in a responsible manner the therapeutic properties and effects of a highly complex prescription medication.

(3) It entails much added expense: Under the provisions of H.R. 11581, lawyers trained in pharmacy and expert in food and drug law, including pertinent sections of the FTC Act, would be needed in passing upon all prescription drug advertising. Similar qualifications would be needed in the case of the advertising copy writers. Such technical authorities would be used by both advertisers and the professional journals. After all, the journal editors and publishers would want to be sure improper drug advertising were never run in their publications. Easily imaginable are the vigorous arguments which would arise between advertisers and publication representatives over whether advertisements complied with the requirements of H.R. 11581.

(C) FACTORY INSPECTION

As drafted, these provisions of H.R. 11581 would empower FDA agents to conduct the broadest kind of search of all places in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, either before or after entry into interstate commerce. Practically speaking, one can hardly imagine Congress granting more unlimited inspection powers over food, drugs, devices, and cosmetics to any Government agency. Such sweeping language would apply to all food and drugstores and hundreds of thousands of other retail and wholesale distributors handling food, drugs, devices, and cosmetics in any form. Retail pharmacists, as an example, would be faced with an army of FDA agents swarming over their business and professional records, including prescription files. And to refuse an FDA agent an opportunity to inspect would be a crime.

The NARD is opposed to the coverage of retail pharmacists by the factory inspection provision of H. R. 11581 for the following reasons, among others:

(1) Already, all retail pharmacists are subject to inspection of their facilities and records by appropriate State authorities. Those inspections by competent and diligent investigators should not be duplicated

by Federal FDA agents. Duplication by State and Federal agents would also be extremely costly as well as quite burdensome to the affected small drug retailers.

(2) Vague, rambling fishing expeditions by FDA agents should be discouraged by Congress, not encouraged. Advise the FDA inspector to seek a search warrant if the party he wishes to inspect refuses permission for a search.

And I might add that there are very few such instances of a drug retailer refusing an FDA inspector an opportunity to make an inspection, but if the agent believes probable cause exists, he can go to court and a warrant will be issued promptly.

I might add that, even now, most retail pharmacists, virtually all, I might add, are happy to cooperate with FDA inspectors by letting them enter the premises for the desired inspection.

As reviewed by the NARD, the committee should give its earnest attention to an amendment adopted by the Senate Judiciary Committee to exclude retail pharmacies. The text of the applicable amendment is as follows:

(1) Pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs, or patients under the care of such practitioners in the course of their professional practice and which do not manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail.

In conclusion, I think it highly significant to point out that a very large majority of the numerous business organizations appearing during your committee's consideration of H.R. 11581 have agreed upon the desirability of strengthening existing Federal drug laws so as to better protect the public health. Almost all have subscribed to the proposed legislation in both principle and purpose, asking only that the bill be carefully studied and, where appropriate, revised to insure that its provisions not be broader than is necessary to bring about a system of better, safer prescription drugs for the American people. With these views, the NARD concurs. We do believe, of course, that H.R. 11581 should be revised to protect the pharmacists' prescription files from Federal inspection and thus bring the bill into conformity with its Senate counterpart.

Thank you very much, Mr. Chairman.

The CHAIRMAN. Mr. Jehle, on page 3 of your statement you propose a change on line 6, page 27 of the bill. The bill now reads "in subsection (b)(4)." with respect to drugs and so forth, and you suggest that it read "in subsection (b) (3) and (4)"?

Mr. JEHLE. Yes, sir.

The CHAIRMAN. (b)(3), I assume, has to do with pharmacists?

Mr. JEHLE. Yes, sir.

It would refer back to page 23 of the bill, line 16, which reads as follows:

Pharmacies, hospitals, clinics, and public health agencies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine.

So the professional exemption, then, if this amendment were accepted, the professional exemption would extend to pharmacies, hospitals, clinics, and public health agencies, as well as to medical practitioners.

The CHAIRMAN. The question that I had in mind is that this change would affect only amphetamines and barbiturates?

Mr. JEHLE. That is correct, sir.

The CHAIRMAN. Mr. Friedel?

Mr. FRIEDEL. Mr. Chairman, I was a little late, but I noticed one thing in Mr. Jehle's last statement which I was glad to hear because almost all other witnesses who have testified are opposed to everything.

You say that this should not be broader than is necessary to bring about a system for better and safer prescription drugs for the American people.

You state you know there is room for improvement, but not to go too far?

Mr. JEHLE. That is correct, Mr. Friedel.

Mr. FRIEDEL. I want to compliment you and also Dr. Cohen, your associate, who, I might mention, is from Baltimore.

I am very happy to see him here.

The CHAIRMAN. We are always glad to have anybody from Baltimore before this committee.

Mr. Younger?

Mr. YOUNGER. Thank you, Mr. Chairman.

In regard to the advertising, I am wondering if possibly something should be worked out somewhere such as the control on investment advertising where they put in an advertisement and then they say this is subject to a circular approved by the SEC.

There they have the circular with all the details, but the details are not in the advertisement.

Do you think that something might be worked out on a limitation of advertising in that manner?

Mr. JEHLE. Yes, Mr. Younger.

I think that some type of accommodation along that line might be worked out, but I think that it will take a great deal more time than the committee has now available to it to work out such a compromise.

We would have no objection to that type of compromise, I am sure of that.

Mr. YOUNGER. That is all, Mr. Chairman.

Mr. JEHLE. It is difficult enough, Mr. Younger, for a national organization that has a lawyer on the staff and competent, experienced people working on the journal, to comply with something like this.

I think it would probably be difficult even for us, but for the publications of some of the smaller State associations and the very small local associations, it would be a virtual impossibility.

They would never be able to pass upon the legality of advertising as required by this proposed legislation.

Mr. YOUNGER. Just one other question.

When Mr. Larrick was before the committee, he said all the States except one had adequate laws governing pharmacies. Do you know which State that is?

Mr. JEHLE. No, sir.